Introduction

MedTech Europe, the European voice of the medical technology industry including diagnostics, medical devices and
(PFAS), as published in January 2023 and subject to initial exchange at ECHA's scientific committees for Risk Asse
MedTech Europe is committed to the ambition of the EU Chemicals Strategy for Sustainability to boost innovation fo
to improve the performance of its products and processes, including through the phase out of uses of PFAS where t

PFAS in the medical technology sector
Where PFAS uses occur in the medical technology sector, this is due to their unique performance and combination
• either in a component or coating of the final medical device (MD) or in vitro diagnostic device (IVD), including inves
•or as a processing aid used during device or upstream manufacturing;
• or in the device part of an integral drug device combination, or as cell replacement therapies, or biomaterials,
PFAS substances play a key role in achieving the required high performance and durability of the technologies whic
(MDs) and Regulation (EU) 2017/746 on In-Vitro Diagnostics (IVDs). These regulations lay down strict requirements

Particular challenges in the medical technology sector
Given the need for such a combination of essential properties, there is often no technical or viable alternative availa
quality requirements. Often the only viable alternative is another type of PFAS. In addition, an alternative must also
etc. according to the stringent sector-specific legislation mentioned above. Without a successful completion of the re

Consequently, MedTech Europe's consultation response substantiates the following sector specific needs to preven
1) A transition pathway to non-PFAS alternatives for medical technologies (including manufacturing and supply chai
these are technically viable, available and in conformity with the sector specific MD and IVD Regulations.
2) A safeguard mechanism for cases where no alternatives are available, and for newly identified non-derogated cas
upstream supply chain.
3) A differentiation between high risk and low risk PFAS considering that Article 68.1 REACH requires a proof of "un
4) A patient-centric approach whereby patient safety needs are considered when transitioning away from PFAS (wh

MedTech Europe' consultation response is structured as follows:
In addition to these general comments, MedTech Europe's response to ECHA's specific information requirements ca
substances (PFAS) in the medial technology sector according to ECHA's guidance "Inputting to the consultation pha
derogations as well as additional identified uses of the sector, which are not part of the ECHA Report at this stage.

How to read MedTech Europe's public contribution to the ECHA Public Consultation on the EU REACH U

MedTech Europe's zip files public submission to the ECHA Public Consultation on the EU REACH U-PFAS Rest

This excel file, which is the first part 1 of MedTech Europe's submission, composed of the following tabs, which a
• Tab 1 (*Introduction*)
• Tab 2 (*How to read*)
• Tab 3 (*Generic elements*): Aims to provide generic elements applicable to proposed derogations and newly add
• Tab 4 (*Aggregation (final)*): Aggregation of specific information (regarding already proposed derogations and id
stage)
• Tab 5 (*Case studies*): Provides a non-exhaustive list of case studies substantiating the need for the suggested
• Tab 6 (*Bibliography*)

A separate PDF document (part 2 of MedTech Europe's submission), compiling a variety of guidance, scientific a

Introduction

MedTech Europe's submission to ECHA's Public Consultation on the EU REACH PFAS Restriction Prop
This tab aims to provide generic elements applicable to proposed derogations and newly added by tl

MedTech Europe members have been working with their suppliers to map where PFAS are currently

Scope or restriction options analysis (e.g. quantity or concentration values)

Use in medical technologies, supply chain and manufacturing:
PFAS can be used either as a component of the final medical device or in vitro diagnostic device (IVD); as a processing aid used during upstream manufacturing or device manufacturing; or as a combination device integrating drugs, biologics, cell replacement therapies, or biomaterials.
The medtech sector relies on its suppliers to also have derogations for the materials and components they supply, but also for the manufacturing processes and aids, otherwise the derogations for medtech "end uses" would become mostly obsolete.
A restriction of PFAS containing substances within the EU may cause suppliers to terminate their production and hence disrupt the distribution of medical technologies within the EU. Additionally, a shortage of possibly alternative materials may arise due to a sudden high demand from several manufacturers.
In the end, this affects patients and customers, because the provision with the respective devices cannot be ensured.

osal is based on the structure described in ECHA's guidance "Inputting to the consultation phase of an An
he medical technologies sector, notably on fluoropolymers. Excel cells that contain more information thar

used in medical technologies and continue to find further examples over time. T **his runs the risk that no**

Hazard or exposure and what risk management measures are in place to minimize human exposure
conformity with the relevant general safety and performance requirements, as well as provide requirements for conducting of clinical investigations. Existing international standards (e.g., EN ISO 14155) address good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical technologies. Manufacturers have established risk management systems (in accordance with EN ISO 14971); as part of the risk management, all known and foreseeable risks, and any undesirable side-effects, are minimised and need to be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. To ensure patient safety, biocompatibility testing has been performed in accordance with the ISO 10993 series: Biological evaluation of Medical Devices, as part of standard medical device risk management requirements. **Information on the use of Fluoropolymers (FP) in medical technologies:** Fluoropolymers and perfluoropolyether biomaterials are commonly used in medical technologies and other biomedical industries. The usage of these materials has been well-proven (over 45 years on the market) and well-regulated (EU MDR approvals and other regions' regulatory approvals). These materials are used in critical device components due to their inherent properties and benefits related to durability, mechanical strength, inertness, thermal stability, and resistance to chemical, biological, and physical degradation. These have been proven to be biocompatible and safe for patient use. Additionally, the following paper provides scientific information regarding the use of fluoropolymers in medical devices as evidenced by toxicology studies on polytetrafluoroethylene: Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035 **PTFE:** Published data, such as that in Henry et al., 2018 cited above (which has been accepted by US, AP and EU medical device regulators), demonstrate that PTFE has a lack of: • low molecular weight oligomers, residual monomer and leachables • toxicity and bioaccumulation.

nex XV restriction report and SEAC draft opinion under REACH", dated November 2020. MedTech Europe's contribution co
ı can be visualised in the row and column width are highlighted in orange for clarity.

t all uses in medical technologies, their manufacturing or in the supply chain for their components have yet been identifi

Environmental emissions and what risk management measures are in place to minimize emissions
Material use: The use case of these fluoropolymers is either for a manufacturing aid or the material remains in the final m where the material may or may not be patient contacting. The use is subject to strict control measures and exte
Fluoropolymers: Fluoropolymers have unique physicochemical properties that constitute a low concern distinction within "chemically stable, biologically stable/inert, negligibly soluble in water, non-bioavailable, non-bioaccumulative; and non-to 1 and 2). Therefore, emissions during the manufacturing processes of medical technologies are controlled accordingly an requirements.
Biocompatibility: Use of device materials must undergo rigorous biocompatibility testing depending on the nature and d per ISO 10993 Biological evaluation of medical devices, as part of the standard risk management pro
End of life management:
According to the sectorial legislations (e.g., EU MDR 2017/745, Annex I, Section 14.7; EU IVDR 2017/746, Annex I, Secti designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substar other person. Instructions for safe disposal are provided in the individual medical technology's Instruction for Use (IFU) Annex I, 23.4 (v).
If the device doesn't have specific disposal requirements due to the manufacturer's risk assessment or another applicabl electronics disposal under the EU regulation on waste electrical and electronic equipment (WEEE)), the IFU commonly ir product in accordance with the locally applicable legislation and the healthcare facilities' biohazard waste procedures. Ho typically treated via incineration.
The Medical Technology sector uses mainly PFAS-containing materials that are applied in articles used in the healthcare e settings. Main PFAS emissions within the control of the sector are emissions during manufacturing, during use and (management.
Degradation emissions of PFAS to air from the incineration of fluorinated polymers is highly dependent on the waste treat of amounts of such emissions, if any, would be subject to the European Industrial Emissions Directive 201
Derogation period:
The proposed derogation periods in the product table varies due to the high level of uncertainty, suc •Whether proposed alternatives meet the required functional properties; •The variety of products, its risk profile and the function of the PFAS containing material in the Medical T •The uncertainty of the future regulatory outlook and the application of the essential use concept, when the PFAS restrict when the proposed derogations expire.
References:
1. Henry, et al., 2018. A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluor Environmental Assessment and Management 14(3): 316-334. http://dx.doi.org/10.1002/ieam.403

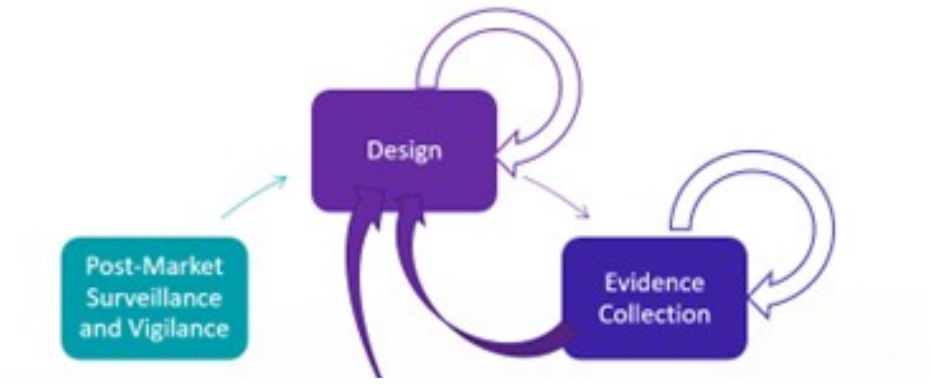
ıent is part 1 of 2.

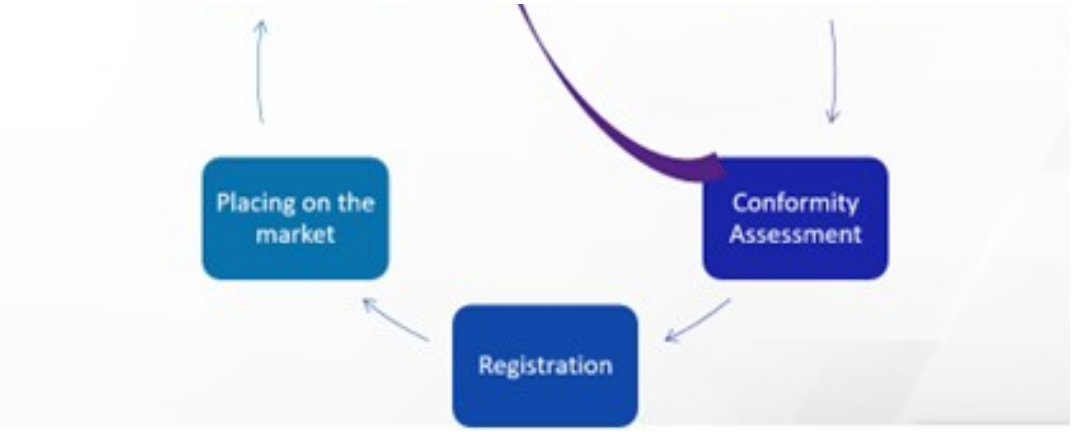
Information on alternatives (e.g., are there alternatives? Are we actively looking for them? What progres

For most applications for medical technologies, there are no, or only proposed options of alternatives. The challenge is t
on its inertness (such as oil, water, temperature, chemical and fire resistance) are the same reason why they are of
A proposed alternative is assessed by material scientists for its possi
If a possible alternative is identified, the whole development cycle has to be followed from analysis and (in silico) evalu
sectorial legislation. When that has been successful the regulatory steps have to be taken before the product can be plac
cycle a rejection of the alternative is still possible and the process will need to start from t
Product, material and chemical innovation is a constant and integrated process in the Medical Technology industry. New
treatment methods and sustainable innovations (e.g. substitution of the most hazardous chemicals). The product life cyc
and required regulatory obligations varies from years to decades, while the chemical and sustainability agenda drives cha
applying the sustainability requirements (including chemical restrictions) on new medical products and granting a time li
the medical and sustainable innovation and ultimately bring new healthcare products mo

<u>Request for a fast-track mechanism to extend the derogation and transitio</u>
If a derogation would be granted, and after the transition period no validated alternative could be identified, there is a n
those cases to ensure continued access to care for patients.

<u>Definitions of alternatives:</u>
Proposed non-PFAS alternatives – proposed alternatives by chemical manufacturers, identified by regulatory agencies, ap
Possible non-PFAS alternatives – proposed alternatives that have been selected by scientists, understanding the function
in the Medical Technology, for further testing and validation.
Validated non-PFAS alternatives – alternatives that passed all validation tests with the conclusion it meets the functional r
(replacing the PFAS containing material), based on the specificities of each device, and not on the material. Once the val
start to bring the amended product to the market, after regulatory app




Placing on the market
Conformity Assessment
Registration

Other SEIA issues (e.g. are PFAS-containing medical devices a risk for the patients

see impacted medical technology uses, and the tab 5 "*Case Studies*").

Depending on the clinical function of the Medical Technology, legacy technology (before it was replaced by PFAS contai available), for the same clinical intervention. In some examples the PFAS containing device enabled a less invasive me intervention will be more invasive and have more impact on the patient and will require lo

Innovation:

If this law were passed, most or all R&D resources would be displaced to support new non-PFAS products, which may a especially if a safe alternative is not possible. The innovative associates dedicated to treating new disease states, seeking solving unmet clinical needs would likely be displaced to seek PFAS-free alternatives. The society, especially patients, wi missing treatment options.

Impact for EU as manufacturing location:

It can be expected that the innovation and development of medical technologies will be transferred to countries outside marketing limits in the EU the ban will impact European medical technology industries in A restriction of PFAS-containing substances within the EU may cause suppliers to terminate their production and her technologies within the EU. Additionally, a shortage of possible alternative materials may arise due to a sudden high In the end, this affects the patients and customers, because the provision with the respective device

Broad Economic Impact:

The material properties of fluoropolymers enable minimal invasive procedures. Patients treated with minimally invasiv recovery time as opposed to invasive or open procedures. A faster recovery time can be reasonably correlated to a sh healthcare sector. A faster discharge may enable a quicker return to the workforce for a given patient. A quicker retur contributing to society, less insurance payments, increased feelings of productivity, maintenance of workplace relation covered by company benefits), among other things.

Sustainability:

With the global push for sustainability, the medical technology sector has been very active in exploring novel methodolo talent is exploring chemical recycling, modular medical technologies, recycled sterilizable packaging, and even re-use of ce also evaluating more sustainable manufacturing practices (such as electronification), carbon footprint reduction, inventi more. It is likely that if this law were enacted, R&D resources would be focused in seeking a fluoropolymer alternative. In the goals of a circular economy, as products in use would have to be scrapped due to the lack of spare parts and

Environment:

Substances within the broad PFAS group represent inherently very different compounds with different chemical, p Fluoropolymers are not the same as certain PFAS that are associated with health or environmental concerns. They are no become widespread in the environment, and do not degrade in the environment, as the use of fluoropolymers does n environment. Those substances should be evaluated and regulated as distinct sub-groups, and not under the

Transitional period/deferred entry into force

The time the medical technology sector requires for a transition to PFAS-free materials depends on vario

- The medical technology sector depends on a multi-tier supply chain and is often a downstream user of components. currently is no obligation for disclosure in the supply chain, the medical technology sector is likely not yet aware of all PFA use or in the manufacturing of those components or their own manufacturing activities.
- A proposed alternative is not the same as a validated alternative (see information under “Information on
- Medical technologies are regulated under stringent sectoral legislation, which lays down requirements for their d performance, alternatives assessment and validation. These are processes that require a significant amount of time an continuous search for alternatives for chemicals proposed for phase-out at EU level.
- Additional factors are the high complexity of products containing PFAS components, and the high number of products substitute concurrently.

MedTech Europe therefore requests sufficient derogation time for the medical technology sector, as no possible alte identification of alternatives up until the confirmation of their feasibility and approval of the related changes may take Column K (Aggregation (Final) tab) for specific transitional period requests based on derogation use

Proposed derogations
5. By way of derogation, paragraphs 1 and 2 shall not apply to:
5(b) textiles used in personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c), until 13.5 years after the EiF
5(c) textiles used in personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m), until 13.5 years after EiF
5(e) textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water and oil repellence
5 (f) refrigerants in low temperature refrigeration below -50°C until 6.5 years after EiF
5(g) refrigerants in laboratory test and measurement equipment until 13.5 years after EiF;
5(h) refrigerants in refrigerated centrifuges until 13.5 years after EiF

5(n) diagnostic laboratory testing until 13.5 years after EiF NEW WORDING PROPOSED BY MEMBERS: diagnostic laboratory testing and diagnostic equipment
5(q) refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF

5(s) lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment

5(ee) the semiconductor manufacturing process until 13.5 year after EiF
The following potential derogations are marked for reconsideration after the Annex XV report consultation:
5bb. [cleaning and heat transfer: engineered fluids for medical devices until 13.5 years after EiF]

5cc. [membranes used for venting of medical devices until 13.5 years after EiF]

NEW WORDING proposed by Members: membranes used for medical devices until 13.5 years after EiF

6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in:

6b. implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF

NEW WORDING PROPOSED BY MEMBERS: invasive and implantable medical devices (not including meshes, wound treatment products, tubes and catheters)

The logic for the expansion is that: since implantable and invasive medical devices have very similar regulatory requirements, given that they pose the highest risk of exposure of all medical device classes, and hence have the most stringent requirements, in terms of the redesign/reformulation efforts that would be needed to bring one of these product to market, containing a new subtance (in this case, without PFAS, which means a new material would need to be substituted for any existing material comprised of PFAS). In fact, invasive and implantable medical devices already receive equal treatment (i.e. derogation) under the EU POPs Regulation (cfr specific text related to PFOA in Annex I, clause 10)

6c. tubes, hoses, washers, sealings and catheters in medical devices until 13.5 years after EiF

Member requested expanding the scope to: apply not only to the tubing itself, but also to the **components/accessories** needed to use the tubing, such as luers, as all of them (tubing + luers) make up the medical device; not only are PFAS used in the tubing, but also the luers (which use PVDF), and if only the tubing is derogated, but not the luers, then we have a major problem, since the medical device consists of both, hence both require the same derogation, since they're both part of the same device, subject to the same overall redesign times needed to bring a non-PFAS alternative to market (i.e. up to 12 years)

The following potential derogations are marked for reconsideration after the Annex XV report consultation

6h. [hernia meshes until 13.5 years after EiF]

6i. [wound treatment products until 13.5 years after EiF]

6j. [coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF]

NEW WORDING PROPOSED BY MEMBERS: coating applications for medical devices in combination products other than Metered Dose Inhalers and for the device part of a drug-device combination product other than Metered Dose Inhalers

6k. [rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF]

6l. [PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 13.5 years after EIF]

The scope should be extended to cover all contact sensitive packaging for medical devices.

6m. [PTFE in ophthalmic solutions packaging until 13.5 years after EIF]

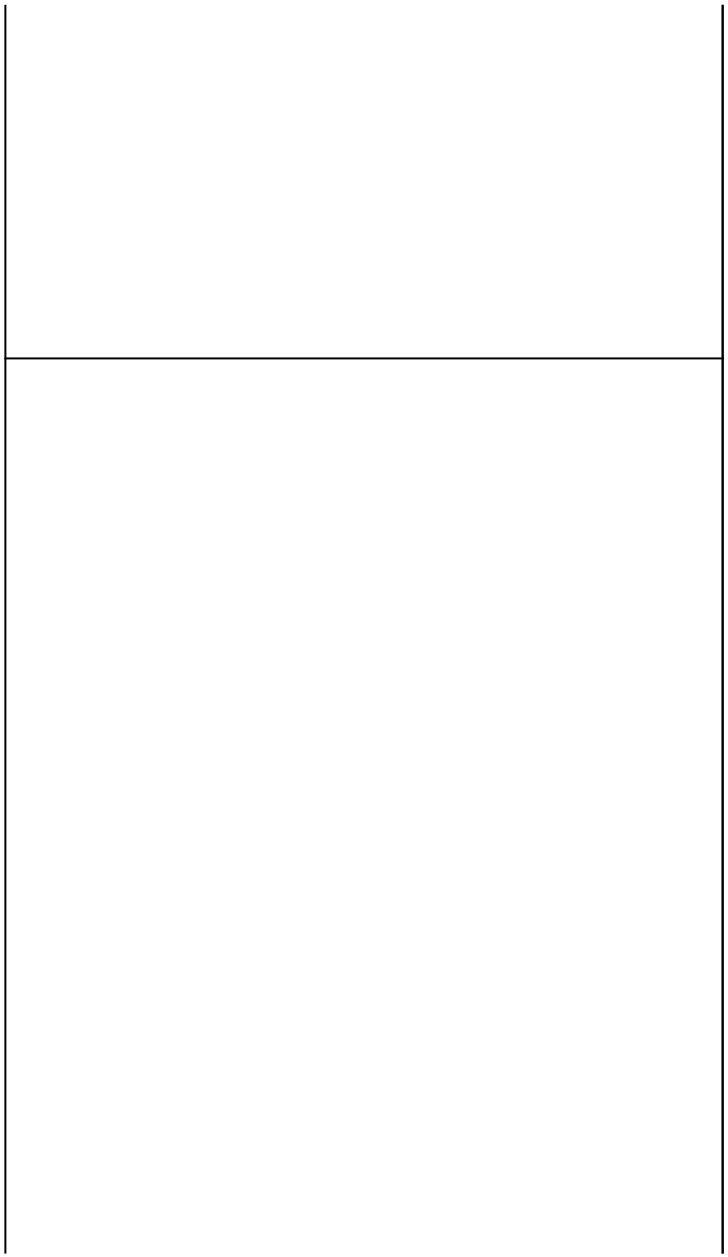
6n. [packaging of terminally sterilised medical devices until 13.5 years after EIF]

ADDITIONAL DEROGATIONS NEEDED

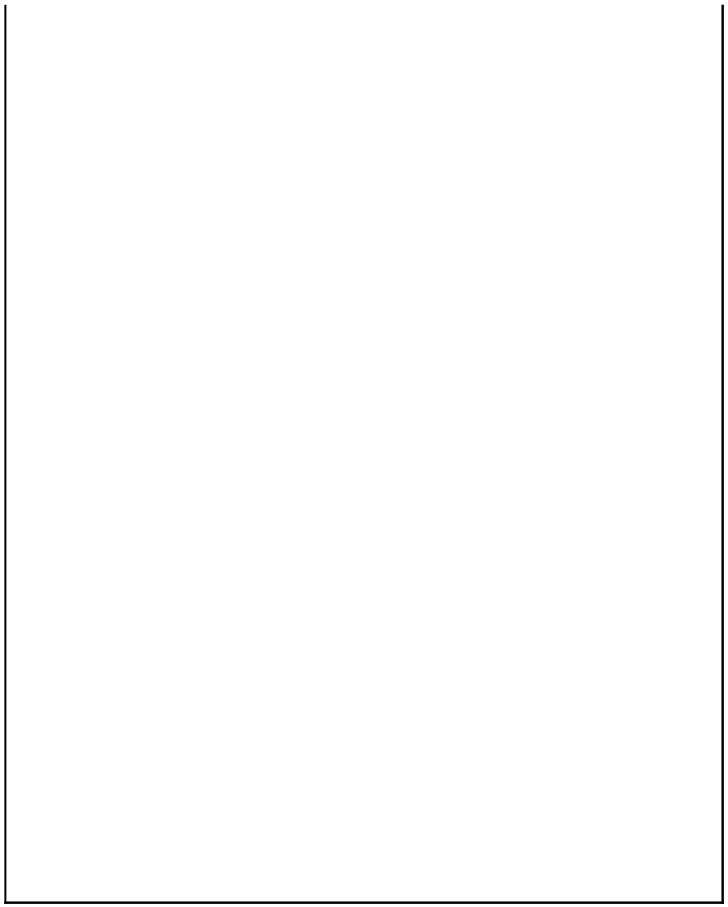
5. Electrical and electronic equipment in medical devices and in vitro diagnostics medical devices, including investigational and devices part of drug-device combination products

5. Sterile packaging applications (for devices and supplies) of medical devices and of in vitro diagnostics medical devices, including similar products such as the device part of a drug-device combination product
5. Manufacturing and processing aid for devices, components and in the supply chain

5. Perfluoron (Perfluoro-n-octane Octafluoropropane (C3F8)
6. Specific applications [not covered by other proposed derogations]



6. Specific (medical technology) components (outside of scope of other derogations)



5. Specific materials

Scope or restriction options analysis (e.g. quantity or concentration values)
Technical textiles include textiles for medical applications. Medical textiles covered under technical textiles refer to any use of textiles in a medical setting, exclu hospital beds, curtains/drapes around beds and gowns used by medical professionals. The derogation should cover all parts of PPE, not only textiles. Fluoropolymers are necessary e.g. for sensors for gas measurement devices and plastic parts (tube pressure, high temperature).
Present within medical devices The derogation should cover all parts of PPE, not only textiles. Fluoropolymers are necessary e.g. for sensors for gas measurement devices and plastic parts (tube pressure, high temperature).
PFAS membranes used for gas or liquid filtration in life science applications are considered to be “technical textiles” ur
The proposed restrictions on Fluorinated refrigerants should be postponed until the outcome of the current parliament discussion on the F-gases Regulation conc and cannot proceed.
CONFIDENTIAL DATA AVAILABLE ON THE QUANTITY The proposed restrictions on Fluorinated refrigerants should be postponed until the outcome of the current parliament discussion on the F-gases Regulation conc and cannot proceed.
The proposed restrictions on Fluorinated refrigerants should be postponed until the outcome of the current parliament discussion on the F-gases Regulation conc and cannot proceed.

Proposed addition to the scope (and derogation)

It is unclear from this proposed derogation if all IVDs under the scope of the IVDR (EU) 2017/746 are covered by this time-limited deroga

• Point of care testing (or, near patient testing, involves any type of diagnostic test that isn't done in the laborato

Examples and reason for use

Substances falling within the group entry under the proposed restriction are used widely in In Vitro Diagnostic Devices in both electronic IVD analysers, in sample t
are critical for the functionality of IVD to perform and conduct diagnostic testing. IVD instrumentation and devices require precision and accuracy when deliverin
materials are chosen to provide friction free, chemical resistant, durable and hydrophobic compatible surfaces for the fluid (patient sample) contact components
allow the sample to be contained within or dispensed from one compartment to another in to be read accurately within the device. Non PTFE tubing can cause

Uses include, and no restricted to: ducting and tubing, filter, fitting, valve, o-rings, washer, plug, lubricants, chemical, heat and moisture resistant coatings, PTFE c
like sliding guides, Industrial production of IVD component, reagents and solutions etc.

PFAS substances are also used in test-strips for Blood glucose monitoring where PFAS is essential to the functioning of the strip to reduce surfa

Chemical compatibility: Performance of O-Rings improves when higher PFAS grades are used in harsh

These guides provide, minimal friction, longevity, no greases that can drip contaminate the liquid samples, no mainte

CONFIDENTIAL DATA AVAILABLE ON THE QUANTITY

The proposed restrictions on Fluorinated refrigerants should be postponed until the outcome of the current parliament discussion on the F-gases Regulation conc
and cannot proceed.

Lubricants: proposed additions to the scope:

a. in medical devices (e.g. for the smooth functioning of the medical device)
b. used as manufacturing aid for medical devices
c. fluorinated lubricants and greases
d. washers in applications where lubricity and protection from degradation
e. wire pulling lubricant

Examples of uses for medical technologies:

Uses for diabetes care: insulin reservoir, smart insulin injector, glucose sensors, transmitter test plugs (fluoro
medical device applications for minimally invasive therapies.
Intensive care ventilation, anaesthesia devices and neonatal care devices

Reason for use:

PFAS lubricant is used for the smooth actuation of functions such as articulation, advancement, and retraction of various various c
Used as a permeable barrier between metallic parts facilitating the sterilization process
PTFE is used in lubricant materials to ensure functionality for the pen injector.
Resistance against high concentration of oxygen in ventilation and narcotic agents in anaesth

Used materials/chemicals:

PFAS materials such as perfluoropolyether (PFPE) and polytetrafluoroethylene (PTFE) are used in lubricants to reduce friction in medical de
There are additional examples of lower molecular weight materials that can perform similarly

CONFIDENTIAL DATA ON QUANTITIES USED IS AVAILABLE

Medical devices require electronic components used in a variety of electronic systems to work. Therefore, the semi-conduct
The use of these materials in semi-conductors enable minimally invasive medical procedures to take place as well as a multitude of other applications. Without this
possible and would have to be replaces with more invasive/ open-heart surgery with significantly more patient trauma. Open-heart surgery processes almost cert
Also the availability of intensive care ventilation devices, anaesthesia systems, neonatal care devices, patient monitors and all hospi

Examples of uses:

1) Surgical instruments with PTFE coating
2) Products include instruments (handle, O-ring) and cases (bases, trays, inserts, etc.)
3) Use as solvent carrier in surface lubrication used for manufacturing of medical device and the device part of an integ
4) Critical cleaning applications, for containers which will be holding reactive chemicals/substances and/or drugs for support of the manufacturing of medical
5) Cleaning of component surfaces manufacturing of medical device and the device part of an integral drug c

Examples of uses: PTFE membrane used for medical application

CONFIDENTIAL DATA ON QUANTITIES USED IS AVAILABLE

Fluoropolymer membranes are also used in other parts of medical devices like gas sensors and gas/liqu

• Poly(ethene-co-tetrafluoroethene, ETFE, PFA) is used as a lead-wire coating to act as an electrical insulator protecting the polyurethane from electrochemically
properties of PTFE, EFTE and PFA also positively affect service life and enable assembly of the lead wire into the poly
• Polyvinylidene difluoride (PVDF) is used as a constituent material in the drug eluting coating applied to all drug-eluting stents (DES). It is used to promote the he
PTFE hydrophilic and innert stent flap coatings allow stent to be removable and to prevent migration. PVDF is used for the same reason on new generation Left A
material on LAAC devices, again to promote healing and better outcomes for patients.
•Implantable heart valve prothesis and transcatheter heart valves. PTFE materials are used in implantable medical devices based on historically proven biocomp
chemicals, liquid sterilant, and ethylene oxide sterilization), and material properties that support implantable prosthetic and transcatheter heart valve functional requ
stability. PTFE fibers provide a low-friction and smooth surface that is less abrasive to native tissue while meeting the required tensile strength and linear densi
materials also provide ease of processing with minimized risk of damaging implant componer
• PTFE as an insulator and as non-conductive epoxy (adhere and insulate) for capacitors which are part of implantable pulse generators (IPGs), electrodes, stylet
and tools to protect delicate parts.
• PTFE membrane. These membranes include non-reinforced, reinforced, and reinforced perforated PTFE membrane variations used in dental bone grafting appl
the non-reinforced versions of these devices. The reinforced, and reinforced perforated versions contain grade 1 titanium in addition to PTFE. The specific density,
tissue interactions that determine predictability and success of guided tissue and guided bone grafting procedures. PTFE membranes are lubricious, impervio
procedures requiring extended healing times. No other devices on the market are available that meet these ne

Additions to the scope:

• Contact/Duration: Blood /Limited Contacting (<24 hours)
• Neurovascular Products: Not part of implantable Stent but part of delivery wire
Use: Introducer Sheaths, Heat Shrinks, liner
Chemical: PTFE and FEP
•Transjugular intrahepatic portosystemic shunt (TIPS) accessories
•Introducer sheaths
•Balloon catheters

Any restriction of Fluoropolymers and perfluoropolyethers (see used materials/chemicals above) will likely cause shortages of a large portfolio of companies. The
health needs will be serviced.

Benefits specific to fluoropolymers in Medical Devices:

• Non-toxic
• Biocompatible (elicits an appropriate response from the host in a given application)
• Chemical resistance
• Heat resistance
• Low coefficient of friction (requires little force for objects to move over it)

Fluoropolymer tubes, hoses, washers and sealings are essential parts in intensive care devices to ensure reliability, durability and patient safety. No other materia
pressure.

Detailed examples and reason for fluruopolymer use:

Minimally invasive delivery system technologies:

Components and assembly aids include the combined uses of PTFE and FEP to provided the proper stiffness, torqueability, and tensile performance characteristi
expanding implants in challenging patient anatomies. Typically, the application of these materials are in the form of a layer of material on the inside diameter of a
diameter of a catheter to reduce friction as a second device is passed within the inside diameter. It also prevents the adhesion of the catheter to the assembly mar
due to their superior lubricity over other materials. The added benefit of reduced coefficient of friction helps to ensure smooth and damage free advancement of te
functionalilty. Additionally, PTFE liners have a high melting point (>600F) and have excellent chemical and bio

PTFE provides the lowest friction coefficient and tightest tolerance tubing for the Finished Good sheath which ensures easy removal from the balloon prior to the d
a tight sheath, which can result in the catheter being stressed during sheath removal and being damaged. Clinical benefit is demonstrated by quantiy of the device
reduction, surface lubricity and low friction act as a key design feature that allows for smooth interaction between different devices used during procedures, and i
catheter liner made of an industrial FP resin, e.g., PTFE, is known for its exceptional surface lubricity, low friction and outstanding hydrophobicity. This results in lo
PTFE allows for extremely low friction and low-profile designs and contributes to low insertion/advancement forces all of which reduce patient trauma. Fluoropo
catheter-delievered heart valve replacements. Patients with heart failure and no access to these products will die, these materials help p

Optical fiber jackets for arterial catheters used in hemodynamic monitoring:

The use of a PVDF jacket on fiberoptic components of cardiac output monitoring catheters protects from moisture ingress during placement of the device in the a
loss of attenuation in the cardiac output measurement signal, which could lead to incorrect measurement readings and subsquent treatments. PVDF and other flu
high hydrophobicity, but also to their flexibility in the tortuous path of the patient anatomy. Finally, the lubricity of the jacket facilitates insertion of the fiber through
breakage of the fiberoptic.

Guidewire coating:

PTFE is the industry standard for guidewire coatings, due to its lubricity, biocompatibility, and strong adhesion to the base material of the wire (e.g. stainless stee
smooth advancement of the catheter during the insertion process and minimizes any vessel damage. The coating allows the clinician to avoid misdi

PTFE provides the lowest friction coefficient and tightest tolerance tubing for the Finished Good sheath which ensures easy removal from the balloon prior to the d
a tight sheath, which can result in the catheter being stressed during sheath removal and being damaged. Clinical benefit is demonstrated by quantiy of the device
reduction, surface lubricity and low friction act as a key design feature that allows for smooth interaction between different devices used during procedures, and
catheter liner made of an industrial fluoropolymer resin, e.g., PTFE, is known for its exceptional surface lubricity, low friction and outstanding hydrophobicity. This
vasculatures. PTFE allows for extremely low friction and low-profile designs and contributes to low insertion/advancement forces all of which reduce patient tra
occluders and catheter-delievered heart valve replacements. Patients with heart failure and no access to these products will die, these material

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The potential derogation covers wound treatment products such as bandages, surgical tapes and surgical staples. However, there are several sutures that are PFT
be in the permanent implant, but are removed as part of the normal use of the product. They are considered essential use for the purpose of friction reduction lub
tubing/catheters. Specialized devices like percutaneous vessel closure devices - Need to confirm/ ensure these uses ar

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Vessel Closure devices allow rapid and secure closure in small bore procedures, which allows patients the ability to early discharge (better for patient health) a
discharge associated with the use of vessel closure devices. In larger bore procedures, vessel closure devices can be the difference between a percutaneous pro

PFAS offer a unique combination of properties that are beneficial in all medical device applications, that is, chemical inertness (will not react with body fluids or che
puncture or stick to surrounding anatomy), softness (critical to patient comfort in sensitive tissues such as those in the mouth), and hydrophobicity (won't hydroly
interstital fluid, etc., so stability in an aqueous environment is critical); generally speaking, only PFAS offer all of these critical properties, and as a result,

Examples of uses:

1) Surgical instruments: PTFE coated
2) Sutures - Polyester thread coated/embedded with PTFE for smoother and stronger suturi
3) Neurovascular Products: Guidewires
Contact/Duration: Blood /Limited Contacting (<24 hours)
4) Trauma: NiPTFE coating of products
5) Coating applications for device part of an integral drug-device combination-iDDC (for example Coated stoppers for prefilled syringes or other t
6) **Insulin delivery system (IDS) consumables:** medical devices for drug delivery (e.g. insulin), Would include insulin pumps,
7) Lowered friction tubes and cannulas

Reasons for use:

Fluoropolymer coated release liners are used in combination with silicone adhesives to produce medical skin contact pressure sensitive adhesives. These adhesive as but not limited to prosthetics, wearable, ostomy or registered and used as transdermal drug delivery systems (combination products) when the adhesive is lo controlled drug release through the skin and support the treatment of diseases such as but not limited to, Parkinson's, Restless legs, Dementia, Neurop

Clinical benefit demonstrated through the long history of use and quantity of devices sold. A consistent user need identified for guidewires is that therapeutic devic to the target site within the anatomy with minimal resistance. This requirement is driven by the friction properties of the proximal end of the guidewire. The gu guidwires, many patients cannot be treated with interventional devices and their life or quality of life will be impacted. Dielectric Strength, required insertion forces feature that allows for smooth interaction between different devices used during procedures, and interactivity between catheters, guidewires, delivery cables. In c discourage bacterial growth, assists with ease of knot-tying, and leads to lower patient trauma. Fluoropolymer use is critical in the safe deployment of heart valv sutures, which provide high lubricity and low patient trauma during implantation. PTFE use in guidewires and thermocouple wires used in medical devices is neces are no alternatives that are acceptable from the standpoint of environment and health, which means it qualifies under
PFAS offer a unique combination of properties that are beneficial in all medical device applications, that is, chemical inertness (will not react with body fluids or che puncture or stick to surrounding anatomy) and hydrophobicity (won't hydrolyze or react with water--the body is mostly water, including blood, urine, interstital fl speaking, only PFAS offer all of these critical properties, and as a result, produce medical devices that are highly

PFAS coating is used e.g. in the insulin reservoir of insulin pumps, due to its chemically inert properties. This eliminates any interacti

Some information on quantity:

We estimate that 2 to 6 tonnes of PFAS are put on the European market annually due to coated stoppers of prefilled syringes. This is based on the estimation that market.

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PFAS offer a unique combination of properties that are beneficial in all medical device applications, that is, chemical inertness (will not react with body fluids or che
puncture or stick to surrounding anatomy) and hydrophobicity (won't hydrolyze or react with water--the body is mostly water, including blood, urine, interstital fl
speaking, only PFAS offer all of these critical properties, and as a result, produce medical devices that are highly

The scope should be extended to cover all contact sensitive packaging for medical devices

PFAS offer a unique combination of properties that are beneficial in all medical device applications, that is, chemical inertness (will not react with body fluids or che
puncture or stick to surrounding anatomy) and hydrophobicity (won't hydrolyze or react with water--the body is mostly water, including blood, urine, interstital fl
speaking, only PFAS offer all of these critical properties, and as a result, produce medical devices that are highly

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puncture or stick to surrounding anatomy) and hydrophobicity (won't hydrolyze or react with water--the body is mostly water, including blood, urine, interstital fl
speaking, only PFAS offer all of these critical properties, and as a result, produce medical devices that are highly

Some examples of uses:

1) Needle Pouches - Puncture resistance needed for terminally sterilized packaging. (PTFE)

2) Various forming films, bags, pouches used for sterile device packaging

3) FP contained package allows terminal sterilization with ethylene oxide gas

4) PTFE identification tags for devices stored in liquid sterliant solution, autoclaved, or undergo ethylene o

Reason for use:

PTFE is due to its extensive biocompatibility history and physiochemical properties to withstand methods of sterilization du

Even medical device packaging benefits from the unique combination of propertiers that PFAS possess, that is, chemical inertness (will not react with most chem encountered during terminal sterilization of medical devices, creating barriers that are highly stable and resistant to break-down or destruction) and hydrophobicity of critincal use or hazard information can be made indellible); generally speaking, only PFAS offer this combination of critical properties, and as a result, produc compromising the sterility of the contents, or otherwise damaging the product or its labeling

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The medical technology sector represents over 500,000 products, services and solutions available on the market. Individual medical devices differ greatly in compl
or thousands of components. In order to build these complex medical technologies, global supply chains use up to 30 tiers when considering the supplier of the
device. The EU REACH Restriction Proposal for per- and polyfluoroalkyl substances (PFAS) includes over 10,000 PFAS substances. Many of these substances a
under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) or in Europe

Electrical and electronic equipment applications in medtech represent some of the most complex assembled medical device technologies. Electrical and electron
those components in itself is very sophisticated, may contain PFAS that are currently not hazardous substances and therefore may not be disclosed. As long as su
whether the provided products, materials, or components contain any of over 10,000 PFAS, it is both known and highly probable that PFAS uses in the manufactur
(EU) 2017/745 for medical devices and Regulation (EU) 2017/746 for in vitro diagnostics medical devices exist in the g

Reasons and examples of uses:

Electrical and electronic medical devices are used for many different uses in the health care industry. One category is continuous monitoring of critically-ill patients
for one company conservatively impacts **CONFIDENTIAL DATA AVAILABLE** EU patients annually. Examples of specific applications of PFAS in electrical and ele
category is Blood Glucose Meters and test strips: in vitro diagnostic system for blood glucose monitoring and linearity test kit for periodic verification of Blood Gluco
used in electrical appliances, also in printed circuit boards (PCBs) due to their flame retardant and heat resistance properties. Also ir

Polytetrafluoroethylene (PTFE) material is used as a protective barrier in re-usable electrical medical devices, such as cables for hemodynamic patient monitoring,
The PTFE protective barrier provides mechanical flexibility and durability properties, moisture protection, and the dielectric strength to prevent electrical current leal
and patients throughout the useful life of the product.

Fluorinated ethylene propylene (FEP) is used as a dielectric barrier in medical devices, such as sensors, for minimally invasive hemodynamic patient monitoring, t
FEP is a unique material that enables critical design requirements for durability and performance such as; flexibility, optically clear for light transmission, low ligh
voids, and biocompatibility.

Fluoromaterials in electronic components:

Fluormaterials, especially ETFE and PTFE are used in electronics components critical to medical devices and IVDs.
Wire jackets/wire insulation in medical devices

Approximate annual amount placed on the EU market:
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Examples of use cases: • Use of PFAS in sterile barrier packaging materials • Packaging of products in scope of EU medical technologies legislations (e.g. EU MDR 2017/745 and IVDR 2017/746, and Directive • Similar packaging of products such as the device part of a drug-device combination produ • Packaging of such products destined for export to non-EU countries where equivalent regulations apply on these products,
1. Fluorinated Polymer Processing Aids (PPAs) in polymerization for continued supply of fluoropolymers, inclu PTFE, PVDF, ETFE, FEP, PFA, which are required in medical devices and capital equipmer
2.Use of PFAS materials in equipment, tooling, manufacturing aids, etc. for testing and ongoing manuf
3. Flouro solvents used as additive in production and quality processes in the manufacture of IVD TFA, TFAA and Pentaflourophenyl trifluoroacetate are considered as the industry standard for the processing and purification of organic components for IVD manu Intermediary components imported into or manufactured in the EU would contain amounts of solvent when placed on the market however these trace amounts co use in industrial and laboratory processes to manufacture reagent components and use in quality processes would be required to be derogated in line wit
4. Mold release of molded thermoset plastics in their manufacture Non-polymeric and polymeric fluorpolymer mold releases are used for a limited number of thermoset pol
5. Polymeric and other PFAS utilized in manufacturing, including tubing and containment vessels, for direct contact with reactive chemicals and substances, whi diagnostic devices including device part of drug-device combination products Properties of the polymeric PFAS including, low coefficient of friction, exceptional barrier properties, excellent chemical resistance (no/low extractables and leachab especially suitable for handling reactive substances. For example chemicals that will cross-link into proper place in the final device (like adhesives or networked g with anything else prematurely.
6. Flouro solvents used as additive in production and quality processes in the manufacture of IVD r

PU/PC Mold release agent 7. Non-polymeric and polymeric fluorpolymer mold releases are used for a limited number of thermoset po
8. Fluoropolymer and other PFAS uses in plant and equipment Industrial production of medical devices, IVD compon Use of PFAS materials in IVD manufacturing facilities is not specifically derogated. The production of IVDs is just as crit There are many use cases of PFAS materials used in these facilities, ranging from water treatment processes, to seals, gaskets, lubricants, teflon coated stir bars lot of the same materials for the same applications got a 6 year derogation. Although, this is probably not even enough time to change out or seel
9. FKM gaskets
The tamponade management aims to support retinal sealing and reattachment following a retinal de 1) Out Patient Procedure: In pneumatic retinopexy, a gas bubble is injected into the vitreous cavity of the eye to treat retinal detachment by utilizing 2) Intraoperative Use. Used in the majority of the >2m vitrectomy procedures globally, tamponade gases are the most commonly used tamponade. Tamponades support retina positio
1. Surgical instruments a. Pads, pivots, and bushings in surgical instruments b. Sleeves in retriever surgical instruments c. high temperature wire used in surgical instruments d. various seals, washers, gaskets, nuts, tapes, lubricants used in surgical instruments e. tubing, tubing connectors, hoses, luer locks used in surgical instruments 2. Cable jacket used for water proofness in sterilizable environments. i.e. cables on the Sterilizable Internal D
3. Lancing Devices: medical device for obtaining blood for self testing purposes (e.g. blood gluc **Reason for use:** PFAS containing materials are used in Lancing Devices due to their friction reducing and resilient properties. These instruments are designed to last ~5000 uses materials are chosen.

4. Dilators and tissue dissectors used during orthopaedic procedures: This derogation is needed to cover the use
5. PTFE in lubricant materials for pen injector functionality **Reason for use:** PTFE is used in lubricant materials to ensure functionality for the pen injector, which can be used by professional
Every medical device specific derogation listed in the existing Annex XV report relies first on the ability to source their components (including those that contain P PFAS tubing, luers, coatings, or a PFAS fluoropolymer article, such as bearings, washers, pipe sealant tape on internal plumbing, etc.--none of these components after we procure them, and incorporate them into the medical device, and we cannot do so, if we cannot procure them in the first place; and even if we can procure at-risk of being eliminated, if we have to move our manufacturing operations outside of EU, in order to be able to procure the materials we need to manufacture ou the EU, only forces us to source from outside the EU, which a company will only do for so long, before they just terminate their EU operations, and move the manu raw materials containing PFAS from say, China, then as a result, our manufacturing operations will eventually move from EU to China, unless we can find a non looking grim at this point, unless we accept as a society that these devices will need to be redesigned using inferiorly performing materials, resulting in devices tha example) or devices that are not as durable (i.e. they break down faster, since we can no longer use PFAS lubricants within their
1. Accessories and spare/replacement parts for medical devices and in vitro diagnostic medical Impacted products include PTFE bend relief for a mechanical circulatory support pump and an acute circulatory support system. Helps to maintain proper orienta IVD instruments placed on market would need to be supported by spare parts and accessories in the field for 20-30 years. Accessories and spare parts would n needeed to continue to maintain the use of these products to ensure continued clinical operat

2.(Medical Device) batteries (Chemical and permeation resistance, Electrical performance charact
3.Heat shrink for invasive medical devices
4.Pads. pivots and bushings in booms and surgical equipment
5. Printing inks that are used to create markings for identification, scale, measurement, size, and other functional attributes on medical devices, diagnostic tests, combination
6. Printing inks for use in harsh environments, for patient sample data integrity PFAS in printing ink provides durable, UV, water resistance for bar codes and other readers
7. O-rings (e.g. in surgical equipment, endoscopy, etc) a. for products used within the sterile field b. in applications where lubricity and protection from degradation
8.Enclosures
9.Filters in medical devices
10. Anti-drip agent
11. Waterproof stickers/ rlease paper/ Labels on medical devices used in wet environment

12. Implantable medical devices components: while implantable medical devices are already proposed for derogation, certain components of these devices are n are critical components needed to use the finished implanted medical device. For example, bone cement itself is implanted, but its delivery system (which contains the fininshed implantable medical device, it is also sold separately and manufactured and procured separately, and hence requires its own separate derogation, oth be made or delivered in practice.
13. PFAS Tape designed specifically for bonding low surface energy plastics and allowing bonding at temperatures down to 0°C, Tape increases productivity emergency response,
14. Non-sterile packaging of medical devices and in vitro diagnostic medical devices
15. PVDF-based membrane material used for the sterile filtration of pharmaceutical, biological and aggressive process gases to prote Scope- device part of an integral drug-device combination-iDDC. The component is PVDF polymer membrane. Product development in prog

16. Shims, washers, and spacers components in medical devices

Reasons for use:

Polytetrafluoroethylene (PTFE) material is used to reduce friction in moving parts within non-catheter components of delivery systems for implantable medical dev
acheive rotational functionality of the delivery system, with lower user input force, necessary to acheive proper implant placement a

Many devices which are mechanical (i.e. contain a mechanism with moving parts, to impart movement of some component of the device) or electrical / electronic
washers and bearings are critical to performance and longevity of the device, since they reduce the amount of friction-wear of its mechanical and electrical /elec
replaced with a non-PFAS material, this can affect the fit and function (and possible the form) of the device, which then requires lengthy redesign and

Other examples of use:

PTFE is also used in spacer rings to provide a low friction, smooth mating surface on rotating hemostasis valve luer fittings, ena

Approximate annual amount placed on the EU market: **CONFIDENTIAL DATA AVAILABL**

1. All fluoropolymers a. Industrial production of IVD component, reagents and solutions b. Fluoropolymers contained in medical devices, and associated manufacturing equipment and proce PTFE, PVDF, ETFE, FEP, PFA are required in medical devices and capital equipment.
2. Use (and manufacture) of PTFE material, but not limited to: a. polymer additives (such as PTFE in molding plastics) in medical devices - e.g. for diabetes insul b. PTFE used for suture c. PTFE in cable wrap protecting sleeve d. PTFE wire e. PTFE Tape f. PTFE lubricants
3.Use (and manufacture) of PVDF materials

Example of use:

4. Analytical Fluorosolvents used for molecular weight analysis of certain polymers, where non-fluoro solvents cann

Materials/chemicals used:

Fluorosolvents used for MWD (molecular weight and its distribution) of polymers

HFIP (CAS # 920-66-1) is the only solvent that dissolves certain polymer and its copolymers at room temperature without polymer degradation for the analysis o property that impacts the mechinal properties of the polymer. Analytical methods ultilize HFIP are being used to monitor the p

Reasons for use:

By dissolving these polymers in HFIP we are able to perform testing, such as molecular weight analysis. This is critically important to clients across a variety of i polymers.

For example, it determines the temperatures used for conversions from solids to viscous liquids, and the strength and to

Without HFIP, determining molecular weight and understanding performance characteristics of certain polymers ju

Not only is this molecular weight analysis valuable for current products and materials but it enables scientists and materials engineers to further develop new produ and engineering.

Hazard or exposure and what risk management measures are in place to minimise
Fluoropolymers are used in PPE to protect workers from hazardous substances. They are chemically inert and do
Risk Management is in line with EU medical technologies legislations (e.g., EU MDR and IVDR) (for human health requireme
Risk Management is in line with EU medical technologies legislations (e.g., EU MDR and IVDR) (for human health requireme
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The only identified potential route of exposure is through dermal contact, which may be possible when handling during assembly and maintenance but would not de happen or considered low, as PFAS materials are contained internally within com The use is subject to strict control measures and external certification requiren
Risk Management is in line with EU medical technologies legislations (e.g., EU MDR and IVDR) (for human health requireme

To ensure patient safety, biocompatibility testing has been performed in accordance with ISO-10993: Biocompatibility of Medical Devices, a

Human exposure to PFAS in fluorinated based lubricants would include:
-Professional user handling (external)
-Exposure via water/food by way of FP degradation products entering the waste stream with
Risk Management measures include:
- Gloves used in sterile/hospital setting

Additionally, the following paper provides scientific information regarding the use of fluoropolymers in medical devices as evide
Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of
Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035+C11

Examples of uses for medical technologies:
Uses for diabetes care: insulin reservoir, smart insulin injector, glucose sensors, transmitter test plug
medical device applications for minimally invasive th+C12erapies.
List as separate derogation request: PTFE in lubricant materials for pen injector fu
Intensive care ventilation, anaesthesia devices and neonatal care device

Reason for use:

Companies report using methods for reducing workplace exposure which include replacing the chemical with a less hazardous one; engineering controls; adminis
sound science and reflect an understanding of the risks posed by the classes of PFASs evaluated. However, the implementation of PFAS risk reduction approache
the supply chain (e.g., negative disclosures, proprietary knowledge). In many cases, importers of products do not have the information to manage the che

Currently, follow methods for reducing workplace exposure which include replacing the chemical with a less hazardous one; engineering controls; administrative
science and reflect an understanding of the risks posed by the classes of PFASs evaluated. However, the implementation of PFAS risk reduction approaches can
supply chain (e.g., negative disclosures, proprietary knowledge). In many cases, importers of products do not have the information to manage the chemi
PTFE membranes used in venting for urine collection. PTFE members used in venting for the IV sets and hazardous drug safety devices and

Risk Management is managed in line with EU MDR regulations and ISO standards, as well as local governance a

Clinical performance or effectiveness and safety of medical devices

Existing regulations (e.g., EU MDR 2017/745 Chapter VI) dictate that manufacturers shall specify and justify the level of clinical evidence necessary to demonstra provide requirements for conducting of clinical investigations. Existing international standards (e.g., BS EN ISO 14155) address good clinical practice for the desig to assess the clinical performance or effectiveness and safety of medical dev

Biocompatibility:

To ensure patient safety, biocompatibility testing has been performed in accordance with the **ISO-10993** series: Biological evaluation of Medical D

Fluoropolymers:

Fluoropolymers and perfluoropolyether biomaterials are commonly used in the biomedical device and other biomedical industries. The usage of these materials ha and other regions' regulatory approvals). These materials are used in critical device components due to their inherent properties and benefits related to durability, r physical degradation. These have been proven to be biocompatible and safe for pa

Literature:

Additionally, the following paper provides scientific information regarding the use of fluoropolymers in medical devices as evide

Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035

PTFE:

Published data, such as that in Henry et al., 2018 cited above (which has been accepted by US, AP and EU medical device

- low molecular weight oligomers, residual monomer and leachables
- toxicity and bioaccumulation.

Risk Management is managed in line with EU MDR regulations (for human health requirements) and ISO standards, as well as lo

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PTFE:

Published data, such as that in Henry et al., 2018 cited above (which has been accepted by US, AP and EU medical device

- low molecular weight oligomers, residual monomer and leachables
- toxicity and bioaccumulation.

Requirements of sectorial legislation to ensure patient safety are fulfil

Conformity with the relevant general safety and performance requirements
Fluoropolymer contained catheter has no toxicity issue to human exposure

Human exposure to PFAS in fluoropolymers would include:

-Professional user handling (external)
-Exposure via water/food by way of FP degradation products entering the waste stream with

Implantable device: Biocompatibiltiy in place to minimize human exposure risks (ISO 10993); chemical characterization testing, we currently follow methods for red
engineering controls; administrative controls or personal-level controls.

In accordance with the hierarchy of controls, a member reports it currently follows methods for reducing workplace exposure which include replacing the chemic
reduce inhalation of the chemical; administrative controls, such as rotating operations to reduce the amount of time an individual worker is around a chemical; or p
Risk reduction approaches should be based on sound science and reflect an understanding of the risks posed by the classes of PFASs evaluated. However, the
industry due to a lack of information of PFAS use in the supply chain (e.g., negative disclosures, proprietary knowledge). In many cases, importers of products do
information-collection challenging.

All devices passed the rigorous biocompatbility tests and demonstrated biological safety. FP is only used in short term (minutes) exposur
(implantable device); Biocompatibiltiy in place to minimize human exposure risks (10993); chemica

In accordance with the hierarchy of controls, a member reports that it currently follows methods for reducing workplace exposure which include replacing the chem
reduce inhalation of the chemical; administrative controls, such as rotating operations to reduce the amount of time an individual worker is around a chemical; or pe
Risk reduction approaches should be based on sound science and reflect an understanding of the risks posed by the classes of PFASs evaluated. However, the
industry due to a lack of information of PFAS use in the supply chain (e.g., negative disclosures, proprietary knowledge). In many cases, importers of products do n
information-collection challenging.

PFAS-containing medical devices and In vitro diagnostic devices used for treatment of patients with diabetes, do not pose a risk for the heath of the patients. The
with strict sectorial legislations (e.g. EU MDR and IVDR) for human health requir

Workplace exposure reduction:

Members report following methods for reducing workplace exposure which include replacing the chemical with a less hazardous one; engineering controls; admini
EU MDR regulations (for human health requirements) and ISO 10993 standards, as well as

Biocompatibility:

Furthermore, guidewires coated with PTFE for minimum friction have been evaluated for their Biocompa

Coated stoppers in integral drug device combination (immediate packaging) (like prefilled syringes) have been evaluated for their biocompatibility and toxicologic
annex I, §10.1 . They have also been evaluated for compatibility with the Drug as per the requirem
Results show that there is no risk to human health.
ETFE coated stoppers for prefilled syringes have been on the market for more tha

Residual solvent level in the devices are acceptable: medical devices and the coating process was evaluated through standard ACR/ECO design

Patient exposure:

The release liner itself is not in direct contact with the patient. The release liner is however considered part of the device /combination product registration: The r
(pharma/device) registration process take into account the Human risk related to the prese

In accordance with the hierarchy of controls, a member reports that it currently follows methods for reducing workplace exposure which include replacing the chem
reduce inhalation of the chemical; administrative controls, such as rotating operations to reduce the amount of time an individual worker is around a chemical; or pe
Risk reduction approaches should be based on sound science and reflect an understanding of the risks posed by the classes of PFASs evaluated. However, the
industry due to a lack of information of PFAS use in the supply chain (e.g., negative disclosures, proprietary knowledge). In many cases, importers of products do n
information-collection challenging.

We currently follow methods for reducing workplace exposure which include replacing the chemical with a less hazardous one; enginee

FP use is not hazardous for human health, concern is with FP building blocks which are short chain PFAS. In Industria

We currently follow methods for reducing workplace exposure which include replacing the chemical with a less hazardous one; enginee

We currently follow methods for reducing workplace exposure which include replacing the chemical with a less hazardous one; enginee
The PTFE identification tag is removed prior to device use, however to ensure patient safety, biocompatibility testing is performed in accordance with ISO-10993:
requirements.

Additionally, the following paper provides scientific information regarding the use of fluoropolymers in medical devices as evide

Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of
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As part of sectorial legislation (e.g. EU MDR and IVDR), whenever a medical device is in contact with a patient or clinical, manufactureres are required to assess t
and clinican safety, biocompatibility testing is performed in accordance with ISO-10993: Biocompatibility of Medical Devices, as part

PFAS-containing medical devices and In vitro diagnostic devices used for treatment of patients with diabetes, do not pose a risk for the heath of the patients. The
with strict sectorial legislations (e.g. EU MDR and IVDR) for human health requir

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To ensure patient safety, biocompatibility testing of all marketed products has been performed in accordance with ISO-10993: Biocompatibility of Medical Devices, biological safety of a medical device is required to be evaluated over the entire life cycle of that medical device. Since aging could impact final product biocompati contact the medical device. This is to ensure there is no harmful leaching of packaging chemicals into the medical device whic
Only trace amounts of fluormaterial are expected to transfer to the molded part. All finished devices me
Polymeric PFAS have minimal hazard or exposure risk. The primary issue appears to be with final disposa

PFAS-containing medical devices and In vitro diagnostic devices used for treatment of patients with diabetes, do not pose a risk for the heath of the patients. The with strict sectorial legislations (e.g. EU MDR and IVDR) for human health require

Fluoropolymers that are used in implantable devices comply with the biocompatibility standards
Fluorinated waxes are present in the Ink formulation used for the marking on the medical devices, e.g., syringes. The exposure to humans is highly unlikely and on incinerated.

The vent pad covering electronic elements contains PVDF. The exposure to humans is highly unlikely and present at t Vent pad is a component an integral drug device combination in development and has been or will be evaluated for biocompatibility and toxicological profile as per also been or will be evaluated for compatibility with the Drug as per the requirement of §10

To ensure patient safety, biocompatibility testing has been performed in accordance with ISO-10993: Biocompatibility of Medical Devices, a

Additionally, the following paper provides scientific information regarding the use of fluoropolymers in medical devices as evide

Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of
Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035

b. PTFE used for suture: The current scope does not take into account a large portion of the dental suture market occupied by PTFE sutures. We request that PT

High molecular weight PTFE is the intended sole component of the suture r

The PTFE polymer is essential to produce a suture rod with the least amount of patient discomfort. Nylon and polypropylene are the only other alternative monc

discomfort due to its soft feel and bio-inertness. It is well established that high molecular weight PTFE is one of the most non-polar, stable, bio-inert materials

The PTFE resin used to manufacture PTFE sutures is certified PFOA free and compliant to ASTM D4895. As such it

The biocompatibility of the finished product has been rigorously evaluated by ISO 10993 and found to

Engineering controls (fumehood, ventilation, etc.), administrative controls (safe handling/training, proper housekeeping, etc

Environmental emissions and what risk management measures are in place to minimise emissions t
Fluoropolymers used in PPE are chemically inert and do not cause any environmental emissions of harr
Medical devices are disposed of in specialised way
Overall, the risk to the Environment from filtration membranes is considered low during their service life. The majority are d

The use is subject to strict control measures and external certification

The use is subject to strict control measures and external certification
The use is subject to strict control measures and external certification

Overall, the risk to the Environment is considered low during the service life of an IVD analyser or device as PFAS materials are contained internally within com
treatment of such instruments at end of life follow the requirements of the WEEE directive

The use is subject to strict control measures and external certification

Role in the supply chain and fluoropolymer use in medical devices:

Many medical device manufacturers are not producers of the underlying chemicals or resins that form the fluoropolymers or other PFAS chemicals in their finish
products or intervening component parts in chemically stable forms, which are then used to manufacture or assemble

Use case fluoropolymers:

The use case of these fluoropolymers is either for a manufacturing aid or the material remains in the final medical device product, where t
One member reports no emissions all fluoropolymers are purchased as pre-molded article

End of life:

Single-use medical devices that utilize tubing and catheters with fluoropolymers are likely incinerated according to h

Environmental testing not readily available for incineration products as process is controlled by h

Manufacturing phase:

Fluoropolymers have unique physicochemical properties that constitute a low concern distinction within the PFAS group as they are “chemically stable, biolo
bioaccumulative; and non-toxic.” [1,2] Therefore, emissions during the use of the materials in manufacturi

Biocompatibility:

Use of device materials must undergo rigorous biocompatibility testing depending on the nature and duration of patient contact, per ISO-10993: Biocompatibility

Safe disposal requirements:

Instructions for proper disposal are provided in the individual medical device’s Instruction for Use (IFU). If the device doesn’t have specific disposal requirements d
the EU regulation on waste electrical and electronic equipment (WEEE)), the IFU instructs to dispose of the product in accordance with the healthcare facility bioha
incineration. Degradation emissions of PFAS to air from the incineration of fluorinated polymers is highly dependent on the waste treatment conditions. 3. Contro
Industrial Emissions Directive 2010/75/EC.

References:

1. Henry, et al., 2018. A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. Integrated Envi
http://dx.doi.org/10.1002/ieam.4035
2. Plastics Europe, Association of Plastics Manufacturers, Fluoropolymers Product Group, Fluoropolymers vs. Side-
3. Wahlström, et al., 2021. Eionet Report - ETC/WMGE 2021/9, Emissions of PFAS to air from the incineration of flu
4. Official Journal of the European Union, DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 o

Final disposal of equipment in compliance with WEEE and local government practives for biohazards. Lik

End of life (Incineration)

The devices will be disposed in biohazardous or medical waste, or incinerated

Role in the supply chain and fluoropolymer use in medical devices:

Many medical device manufacturers are not producers of the underlying chemicals or resins that form the fluoropolymers in their finished devices. These devic
component parts in chemically stable forms, which are then used to manufacture or assemble life-saving

Use case:

The use case of these fluoropolymers is either for a manufacturing aid or the material remains in the final medical device product, where t

Manufacturing phase: Physicochemical properties of Fluoropolymers:

Fluoropolymers have unique physicochemical properties that constitute a low concern distinction within the PFAS group as they are “chemically stable, biolo
bioaccumulative; and non-toxic.” [1,2] Therefore, emissions during the use of the materials in manufacturi

Use phase: Waste handling information supplied with medical devices:

Use of device materials must undergo rigorous biocompatibility testing depending on the nature and duration of patient contact, per ISO-10993: Biocompatibility
Instructions for proper disposal are provided in the individual medical device’s Instruction for Use (IFU). If the device doesn’t have specific disposal requirements d
the EU regulation on waste electrical and electronic equipment (WEEE)), the IFU instructs to dispose of the product in accordance with th

End of life phase: Waste treatment conditions:

Hospital biohazard disposal is typically treated via incineration. Degradation emissions of PFAS to air from the incineration of fluorinated polymers is highly dep
emissions, if any, would be subject to the European Industrial Emissions Directive 2010/75/E

References:

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4. Official Journal of the European Union, DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 o
5. The Institute of Technical Chemistry at KIT, Germany, did an incineration study of PTFE for potential releases of a broad range of PFASs in municipal was
acceptable way to dispose of the fluoropolymer and does not pose an environmental conce
(Published in scientific journal, Chemosphere, Volume 226, July 2019, Pages 898-906. <https://www.sciencedirect.com/scien

Emissions from the medical device sector:

Per Annex XV Table 1, annual polymeric PFAS used in the medical device industry makes up only 2.75% of the total (mid) estimated amount used across the
devices, at 0.38% of all polymeric PFAS emitted to the environment across all major use sec

End of life treatment of medical devices

Likely through incineration of disposable devices, e.g. catheters, after clinical use, will be disposed according to the applicable r

Single-use medical devices that utilize tubing and catheters with FP are considered hazardous waste to which special waste regulations apply. To our kn

Role in the supply chain and fluoropolymer use in medical devices

Many medical device manufacturers are not producers of the underlying chemicals or resins that form the fluoropolymers in their finished devices. These devic
component parts in chemically stable forms, which are then used to manufacture or assemble life-saving

Use case

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Manufacturing Phase: Physicochemical properties of Fluoropolymers

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Use phase: Waste handling information supplied with medical devices

Use of device materials must undergo rigorous biocompatibility testing depending on the nature and duration of patient contact, per ISO-10993: Biocompatibility
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End of life phase: Waste treatment conditions

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Device is implanted into the patient typically for life. Possibly removed from patient if complications but would be disposed of in biohazard or medical waste. Expi
scrapped according to local regulations. **CONFIDENTIAL DATA ON QUANTITIES USED IS AVA**

Emissions/release associated with implantation of hernia meshes is minimal, as the only potential emissions would come from trimmings during surgery. If the regu
opt to exit this market space entirely in the EU.

Most likely through incineration; or disposed in biozard or medical waste.

Emissions from the medical device sector

A member reports that for medical device coating applications using PFAS fluids (which are in themselves costly), there are capture and recondensation systems t
with patient's fluid path therefore will be disposed in biohazard or medical waste or incinera

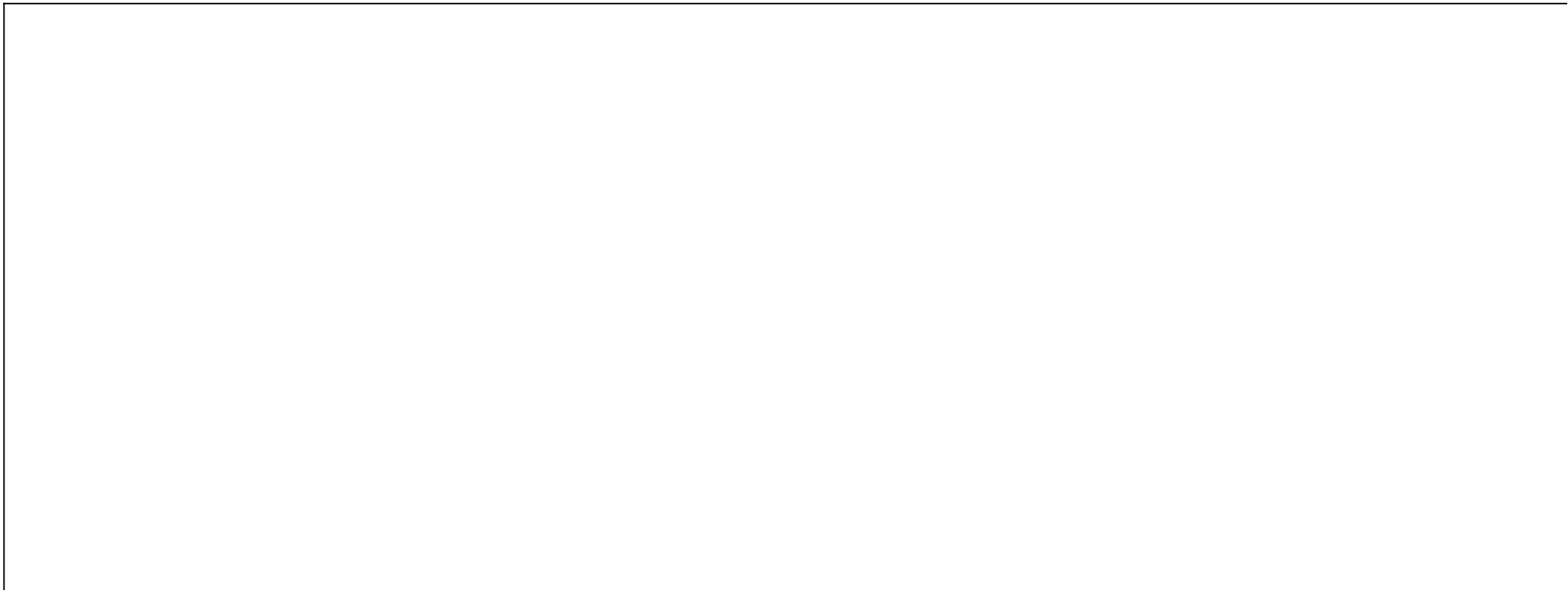
Contactors or disposal (unclear in case of burial), manufacturing sites are certified to ISO 14001. This requirement is met using a Risk Management quality syste
(ISO 14971). The Institute of Technical Chemistry at KIT, Germany, did an incineration study of PTFE for potential releases of a broad range of PFASs in municipa
acceptable way to dispose of the fluoropolymer and does not pose an environmental concern. (Published in scientific journal, Chemosp
<https://www.sciencedirect.com/science/article/pii/S0045653519306435>); Per Annex XV Table 1, annual polymeric PFAS used in the medical device industry m
major use sectors. The emissions percentage is even lower for medical devices, at 0.38% of all polymeric PFAS emitted to the e

CONFIDENTIAL DATA ON QUANTITY IS AVAILABLE

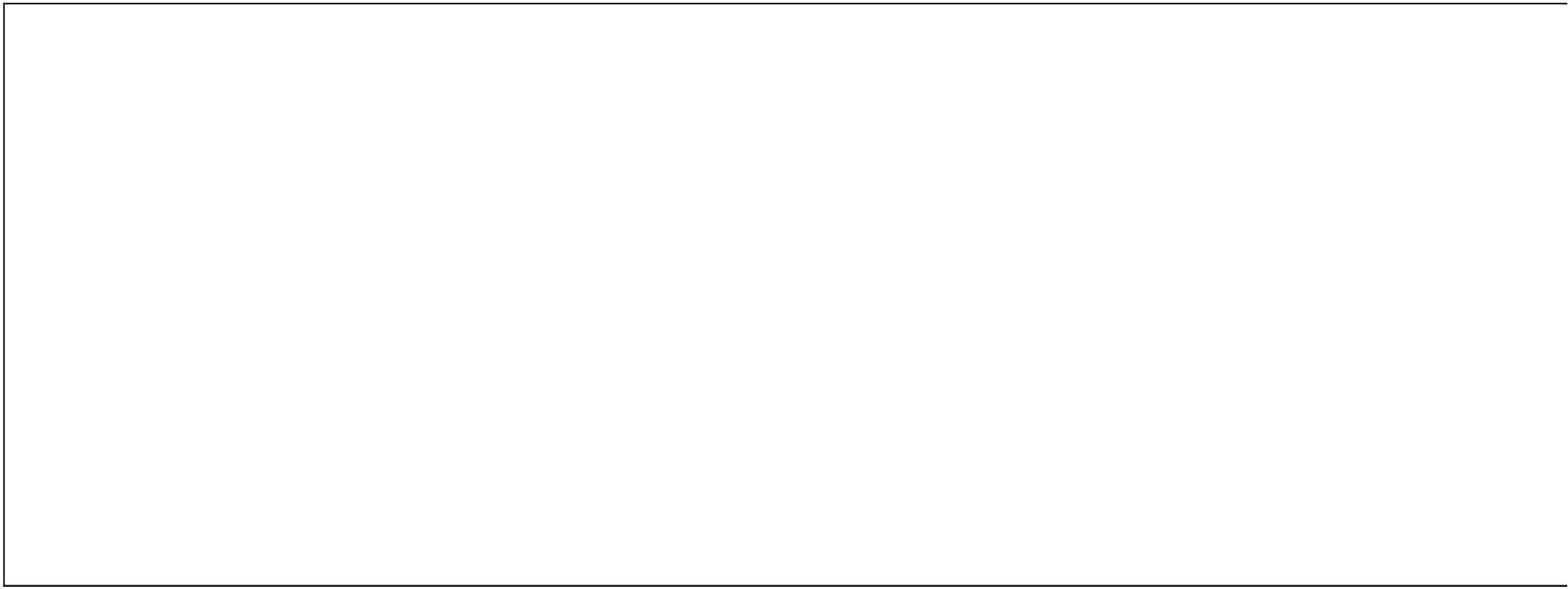
End of life phase: Waste treatment conditions

e.g., PFAS coating device part of an iDDC (integral Drug device combination) is coming in direct contact with patient's fluid path therefore will b

Devices coming in direct contact with patient's fluid path will be disposed in biohazard or medical waste or incinerate. All FP are purchased as part of fully formed a
FP-related emissions expected. Devices containing FP coatings are either incinerated, returned, or, in the case of deceased patients, left in the patient and subse
products as process is controlled by hospitals. When used from home by consumers it is not excluded that the release liner can be



PFAS emissions from the service life of the packaging is considered to be low.



End of life (Incineration)

Many medical device manufacturers are not producers of the underlying chemicals or resins that form the fluoropolymers in their finished devices. These devic
component parts in chemically stable forms, which are then used to manufacture or assemble life-saving

Use case:

The use case of these fluoropolymers is either for a manufacturing aid or the material remains in the final medical device product, where t

Fluoropolymers have unique physicochemical properties that constitute a low concern distinction within the PFAS group as they are “chemically stable, biolo
bioaccumulative; and non-toxic.”1,2 Therefore, emissions during the use of the materials in manufacturi

Use of device materials must undergo rigorous biocompatibility testing depending on the nature and duration of patient contact, per ISO-10993: Biocompatibility

End of life phase: Waste management

Instructions for proper disposal are provided in the individual medical device’s Instruction for Use (IFU). If the device doesn’t have specific disposal requirements d
the EU regulation on waste electrical and electronic equipment (WEEE)), the IFU instructs to dispose of the product in accordance with the healthcare facility bioha
incineration. Degradation emissions of PFAS to air from the incineration of fluorinated polymers is highly dependent on the waste treatment conditions.3 Control
Industrial Emissions Directive 2010/75/EC.4

References:

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2. Plastics Europe, Association of Plastics Manufacturers, Fluoropolymers Product Group, Fluoropolymers vs. Side-
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Many medical device manufacturers are not producers of the underlying chemicals or resins that form the fluoropolymers in their finished devices. These devic
component parts in chemically stable forms, which are then used to manufacture or assemble life-saving

Use cases:

The use case of these fluoropolymers is either for a manufacturing aid or the material remains in the final medical device product, where t

Reasons for use:

Fluoropolymers have unique physicochemical properties that constitute a low concern distinction within the PFAS group as they are “chemically stable, biolo
bioaccumulative; and non-toxic.”1,2 Therefore, emissions during the use of the materials in manufacturing is negligible. Certified waste treatment in EU is via en

Disposal: Use of device materials must undergo rigorous biocompatibility testing depending on the nature and duration of patient contact, per ISO-10993: Bioco
process. Instructions for proper disposal are provided in the individual medical device’s Instruction for Use (IFU). If the device doesn’t have specific disposal rec
disposal under the EU regulation on waste electrical and electronic equipment (WEEE)), the IFU instructs to dispose of the product in accordance with the healt
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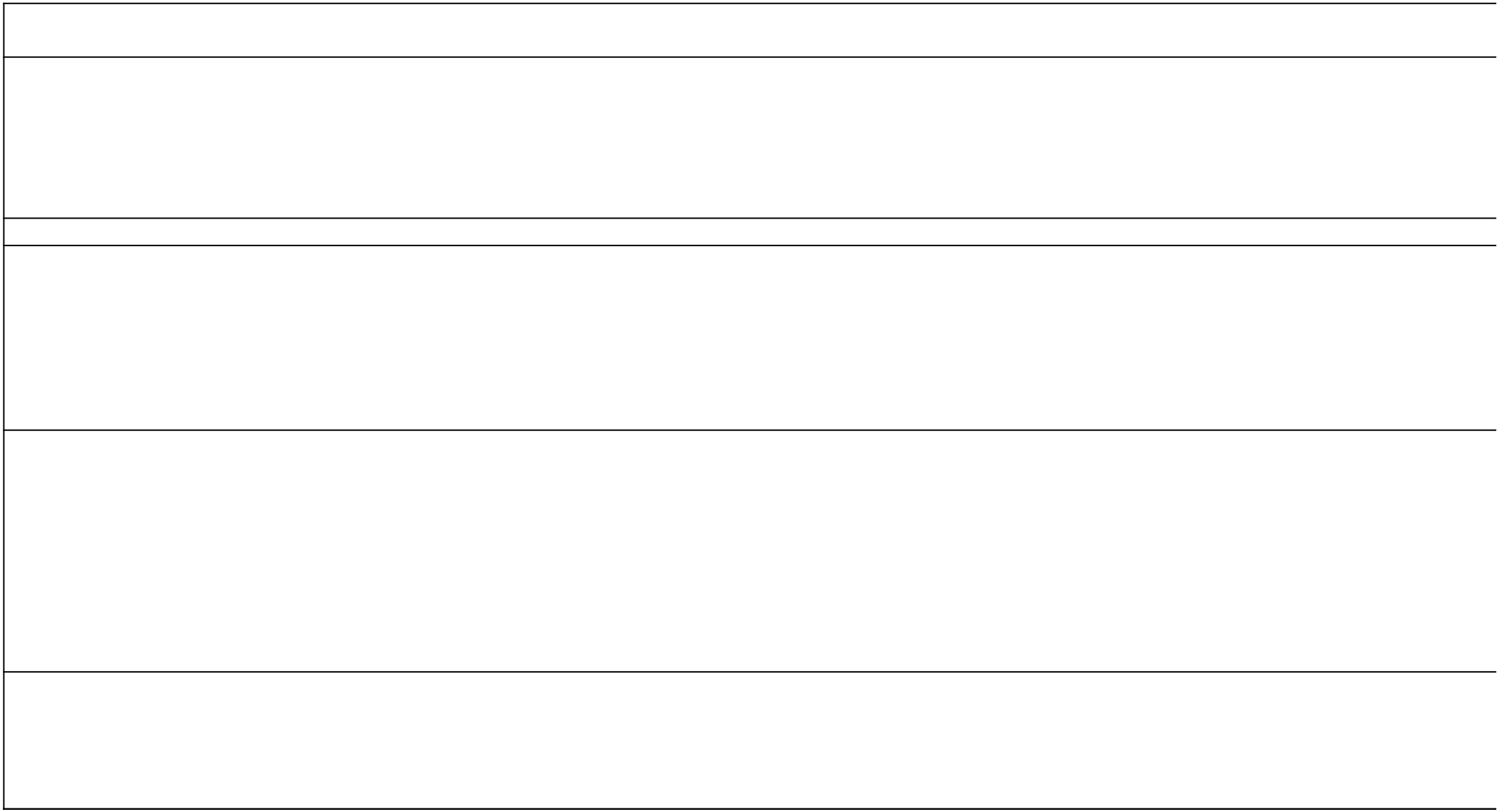
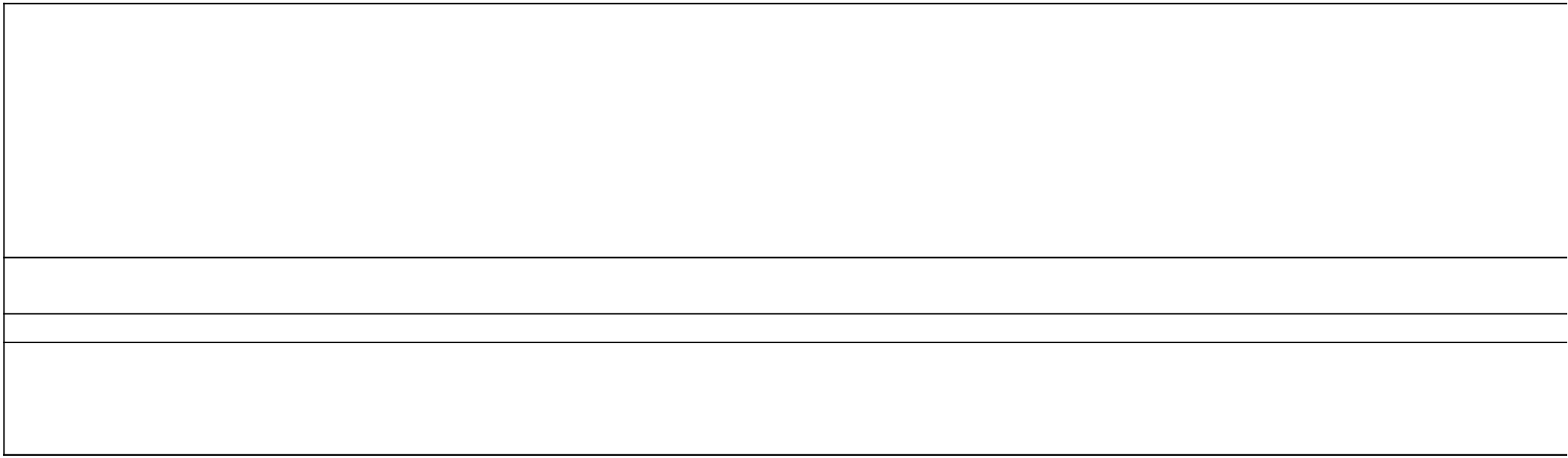
4. Official Journal of the European Union, DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 o

Final disposal of equipment in compliance with WEEE and local government practives for biohazards. Likely incineration. Capital equipment iparts may be re



All fluoropolymers are purchased as fully formed articles (i.e. pre-molded/pre-extruded components) therefore no fluoropolymers-related emissions expected. Impla patients, left in the patient and subsequently buried.
The devices where it is used are mostly single use and will be incinerated after the use.



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Final disposal of equipment in compliance with WEEE and local government practives for biohazards.
Likely incineration.
Capital equipment parts may be returned to supplier in the US for replacement, refuribishment or resale

b. PTFE used for suture:

Disposal: It is well supported in the literature that high molecular weight PTFE, such as that composing PTFE sutures, does not degrade in the environment or
(Henry, 2018). As these products are short term implantables that contact bodily fluids, the vast majority of them are disposed of in biohazard waste streams whic
Karlsruhe Institute of Technology have researched the bi-products produced by the incineration of PTFE and found that PTFE burned at temperatures typical of a
dioxide. It was their conclusion that "Municipal incineration of PTFE using best available technologies (BAT) is not a significant source of the studied PFAS and sh
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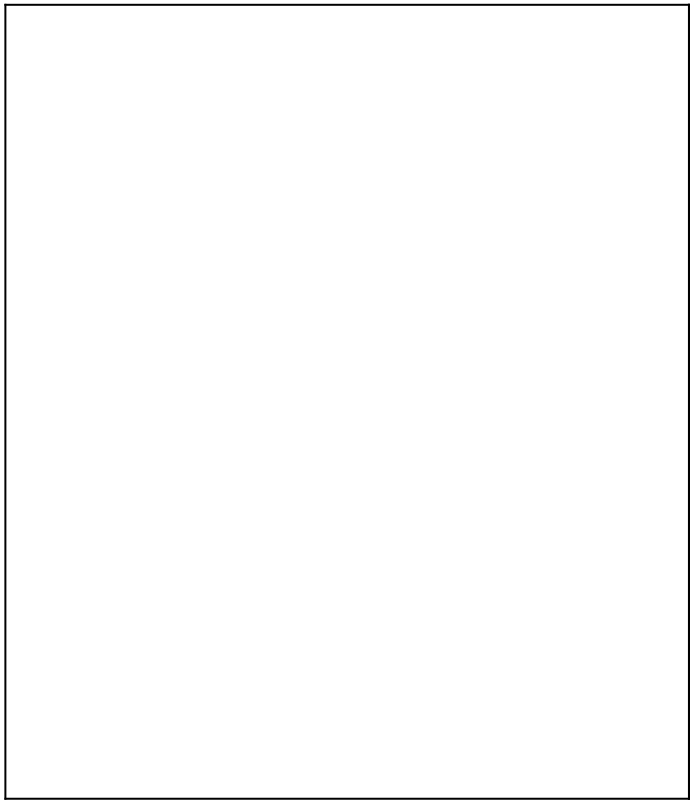
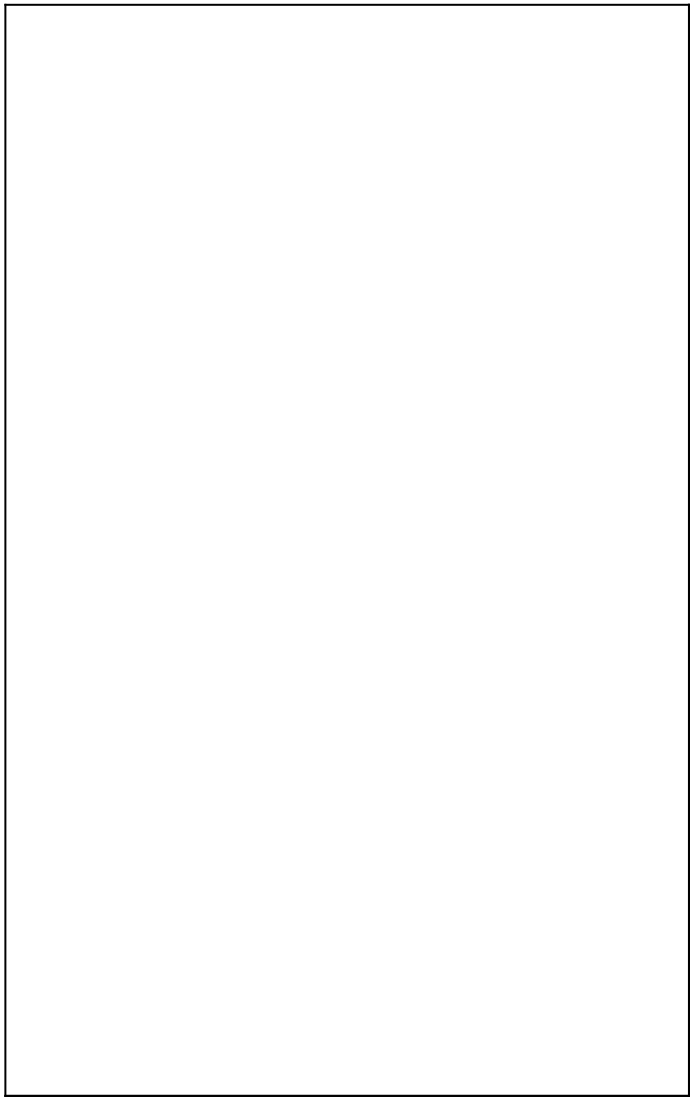
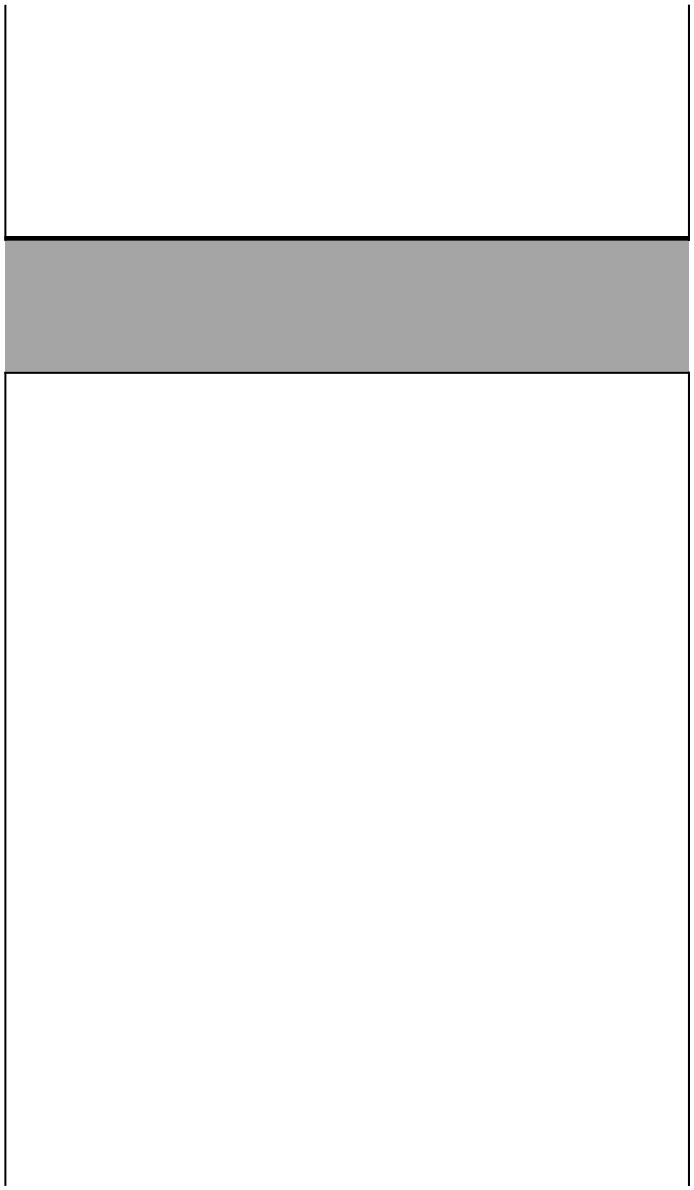
was their conclusion that "Municipal incineration of PTFE using best available technologies (BAT) is not a significant source of the studied PFAS and should be

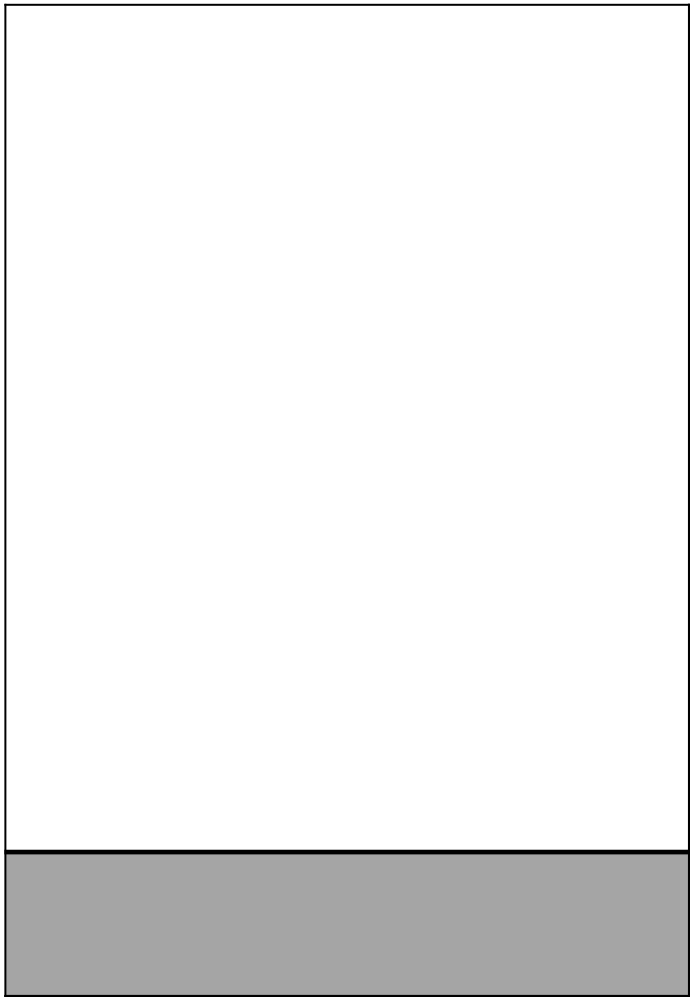
As per internal procedures, waste solvents are sent it to 3rd party for treatment and dispos

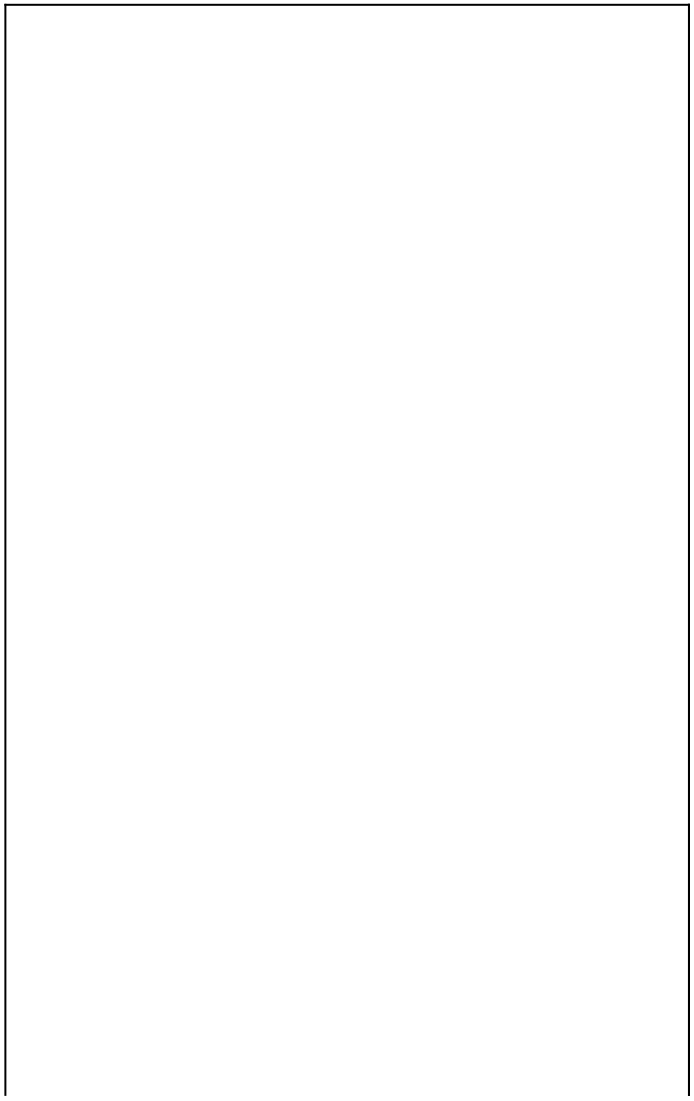
Baseline











We understand the need to scrutinise the use of toxic PFAS, i.e., those that are CMR and/or endocrine disruptors.
But polymeric PFAS (i.e. PTFE, PVDF, FEP,…) which are regarded by the OECD as safe materials ("PLC" = polymer of low concern) should be excluded from the proposed ban for all application sectors.

Up to 10 years are needed for alternatives to PFAS

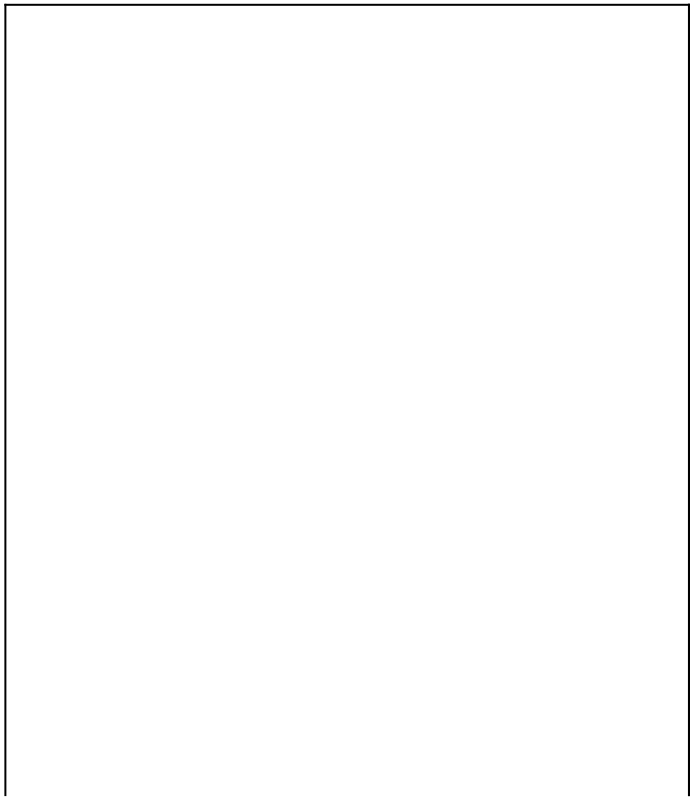
It would take up to 10 years to identify, develop and validate alternative to PFAS containing material

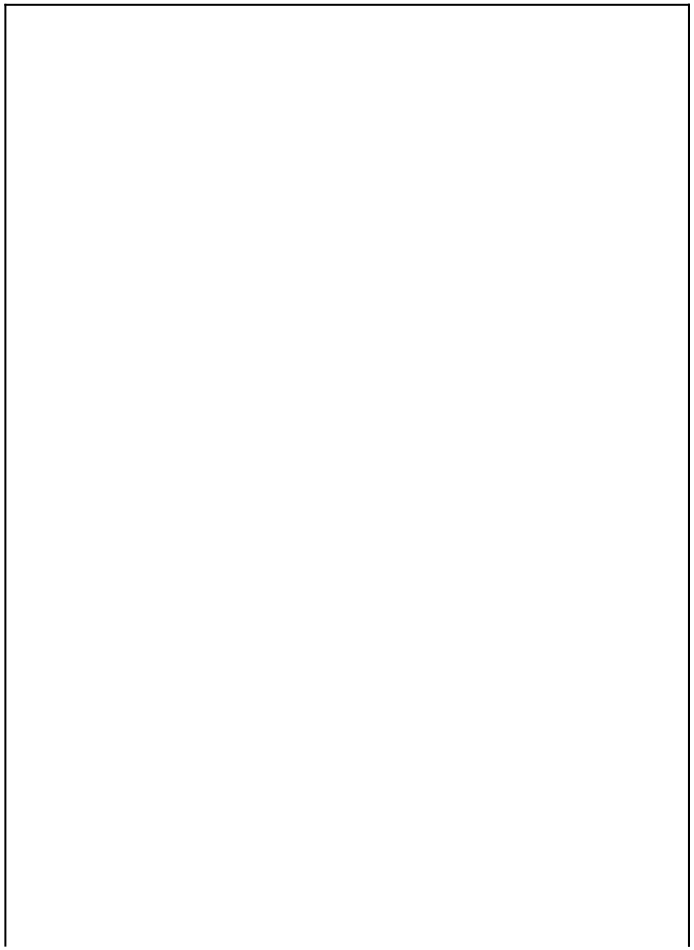
PTFE hydrophilic coating on wires and sphintertomes to reduce friction and prevent tissue trauma. Also for lowering friction during dilation balloon delivery. Without PTFE there is a far higher probability of the products becoming snagged as they push through complex anatomical geometries.

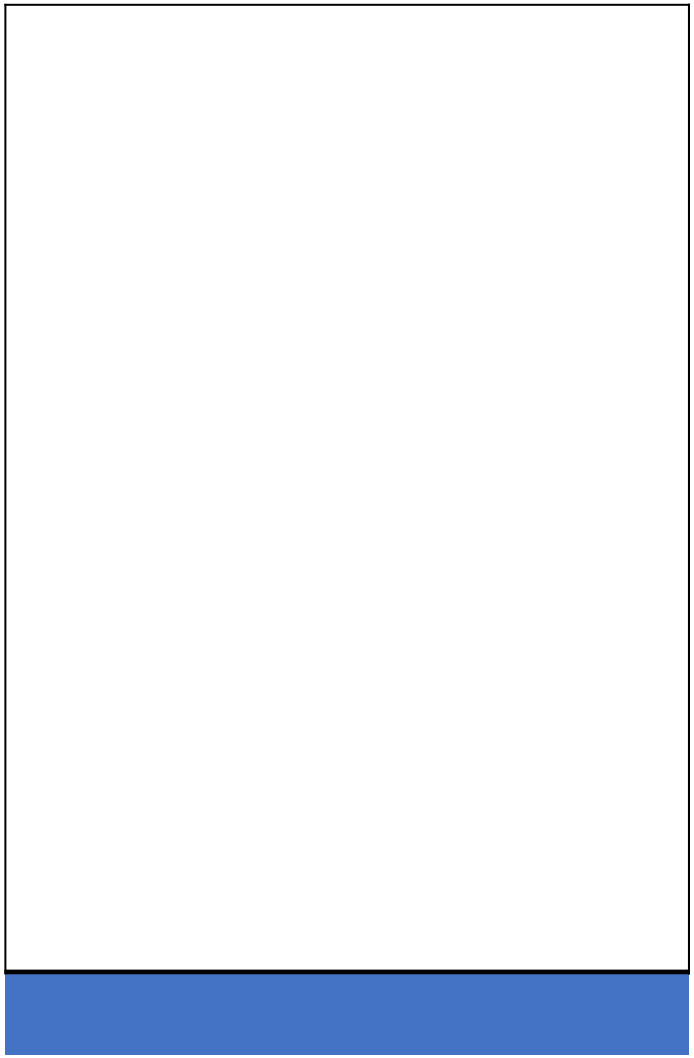
Wires coated for lubricity - Sensor, Amplatz, Percuflex, Flexima, Clot Hunter

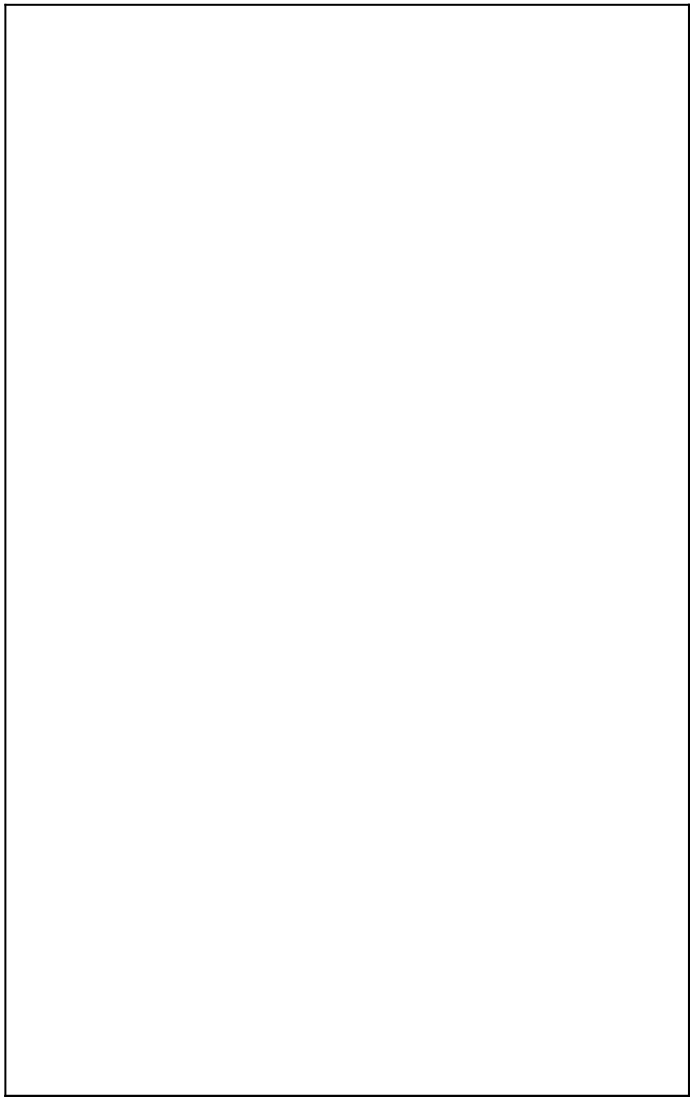
Hhydrophilic coating for sphinctertomes - Jagwire, TrueTome; Legacy DES devices (Promus & Some Synergy Devices).

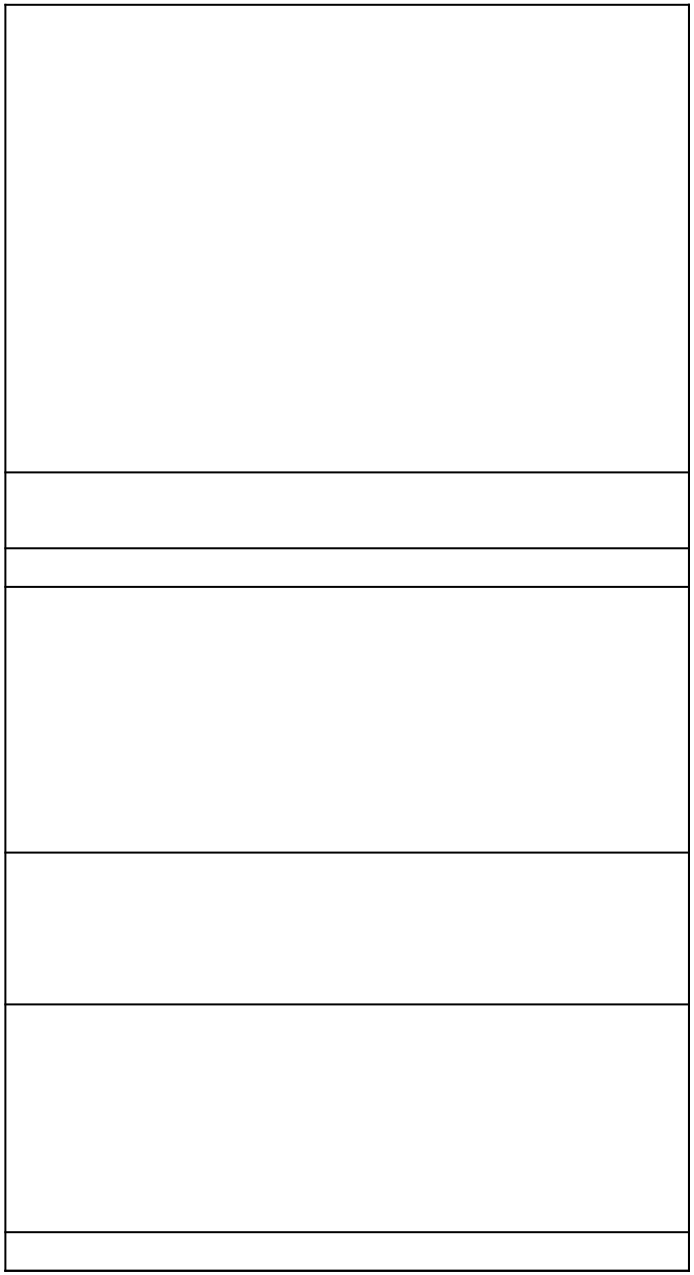
However even if some iDDC are listed in the examples (like prefilled syringes) the derogation wording is ambiguous and we would like to have it clarified to confirm that iDDC are included and not only Medical devices.

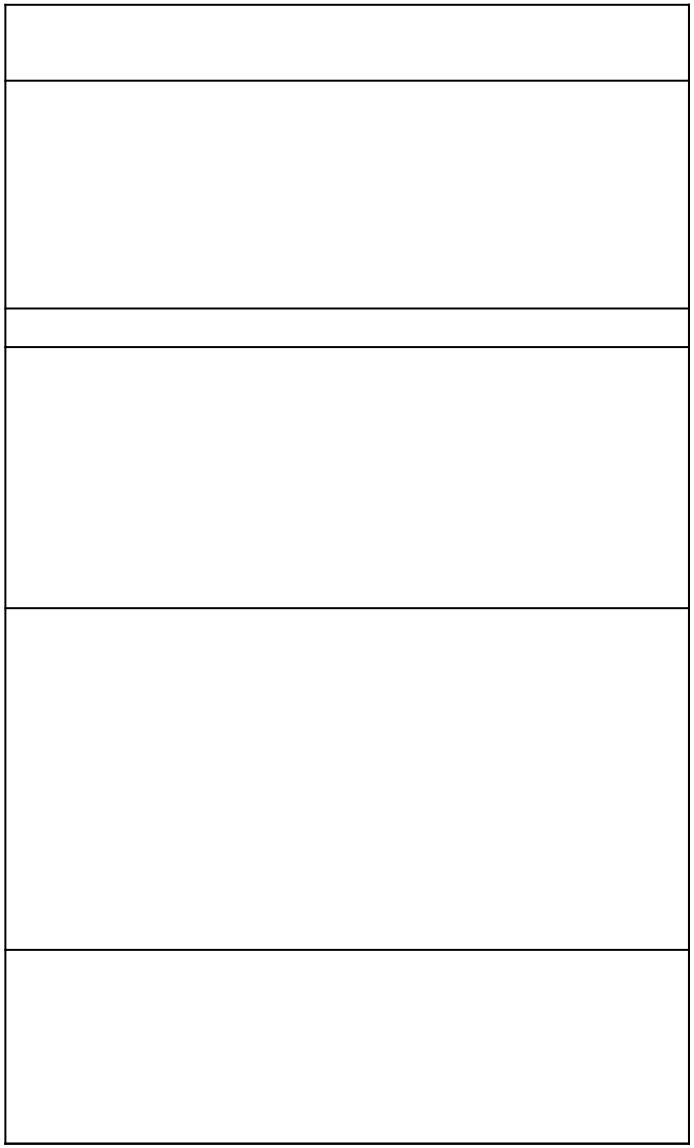


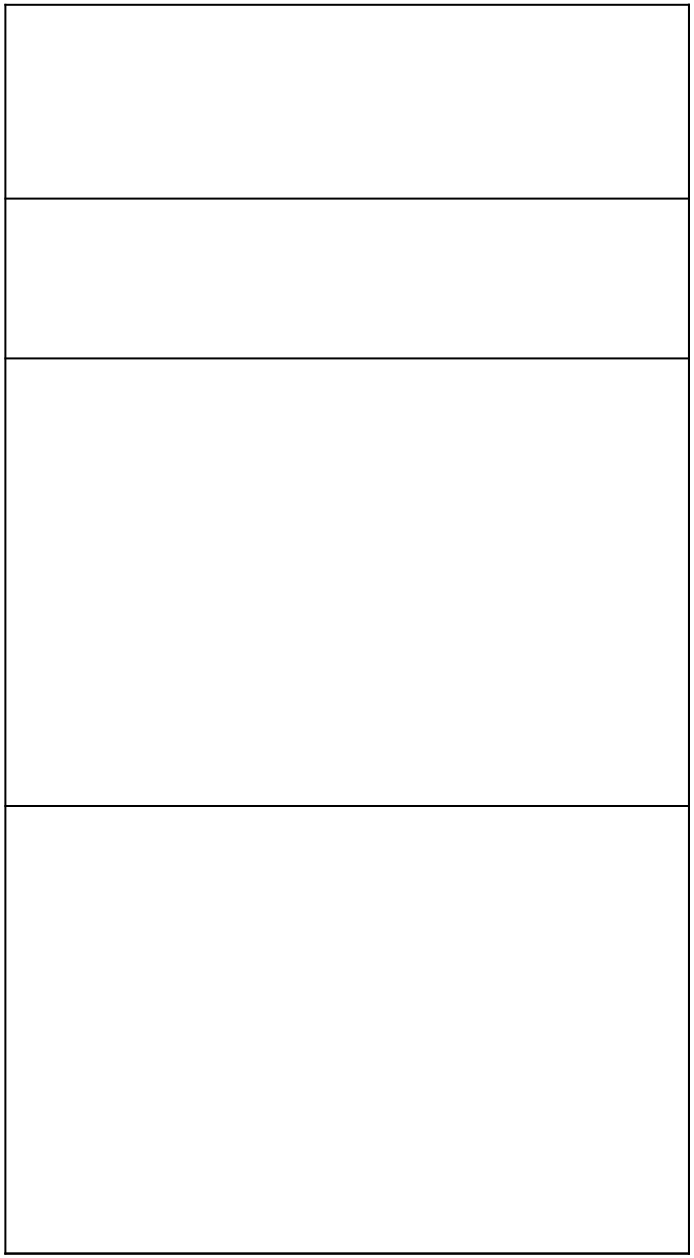




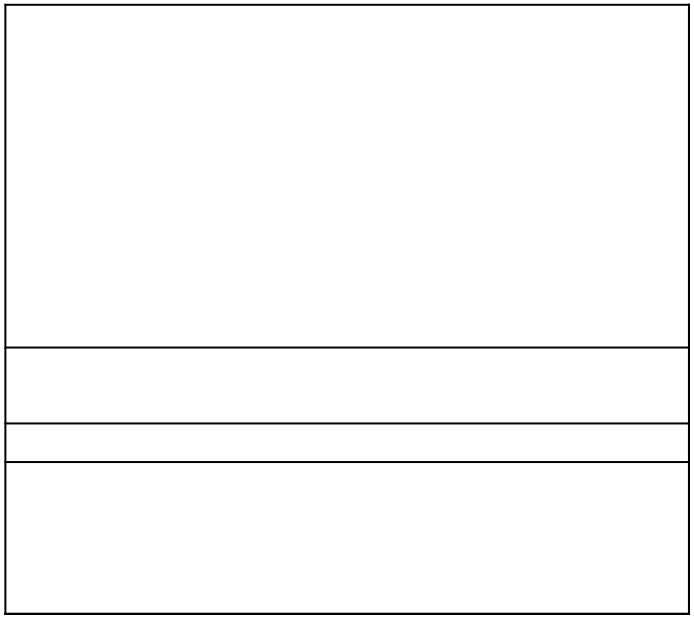


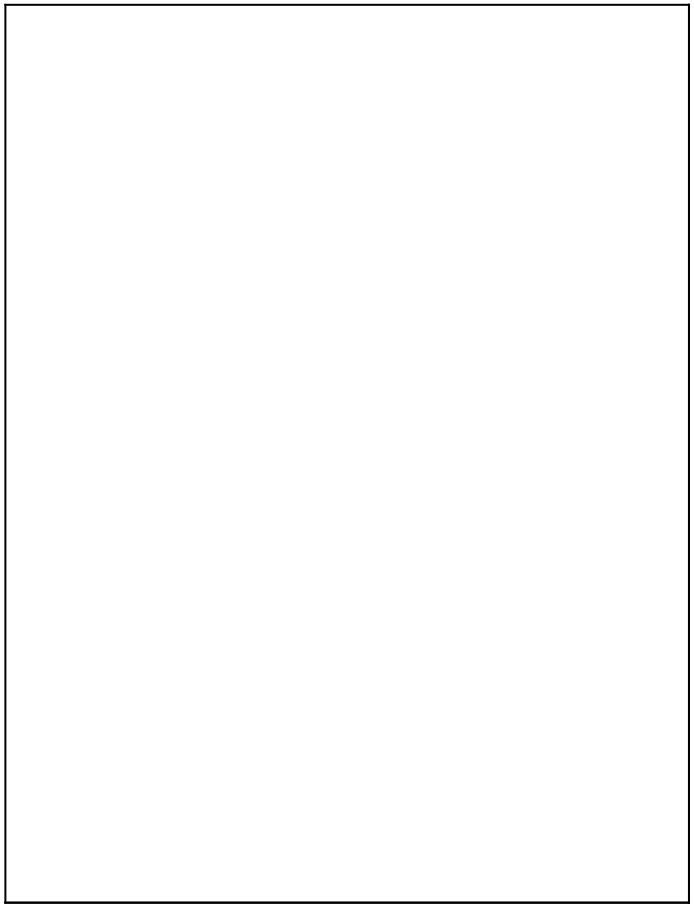




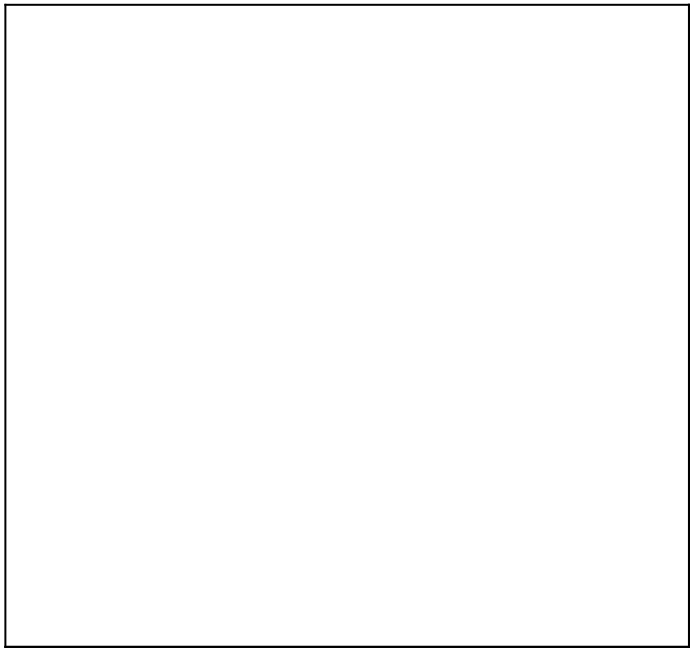


A derogation of 13,5 years after EIF is needed to evaluate alternatives, validate and qualify the most promising alternative.





Without these applications of fluoropolymers less invasive procedures would not be possible and would have to be replaced with open-heart surgery with significantly more patient traume. Open-heart surgery processes almost certainly rely on other fluoropolymer applications suchs as coated sutures.
b. PTFE used for suture: A ban would be contraproductive and lead to currently unknown risks for health and environment. We relay on scientiifc data to implement risk control measure to protect health and environment . The lack of knowledge on potential impact caused by alternative solution is not sufficently demonstrated and may cause further decateds of potential contamination and harm of healt and impact on environment. The current risks, especially with PTFE are understood and can be mitigated due to the scientifc background and over decaeds of investigation and development currently known to eleminate PFAS.



Description of analytical methods

Per proposal pgs 170-173, fluoropolymer articles and fluoropolymer-coated articles will require both Total Organic Fluorine (TOF) and targeted non-polymeric PFAS analysis (direct quantification by LC-MS/MS using the ~40 existing PFAS reference standards) to evaluate the source of measured fluorine as either PFAS or non-PFAS, with a proposed total fluorine limit of 50ppm. TOF test will also apply to other PFAS substances.

Polymeric articles and coated articles can be manufactured without detectable residual concentrations of non-polymeric PFAS processing agents. Fluoropolymer articles and coatings consist of significant amounts of organic fluorine, far exceeding the 50ppm (0.005%) limit (PTFE/Teflon for example is approximately 80% fluorine w/w).
The proposed restriction is essentially a de facto fluoropolymer ban.

Surface analysis systems:

Surface analysis systems have a detection limit ranging from 1000 – 3000 ppm and 10-50 ppm respectively. Sample preparation and sample size are crucial for accurate detection (e.g., XRF is only able to detect and quantify Fluorine using a Helium flush). Targeted analysis like LC-MS, GC-MS, LC/MS/MS or GC/MS/MS systems require arduous sample preparation that typically involves Solid Phase Extraction or SPME, solid-liquid and liquid-liquid phase extraction to enhance accuracy and precision of the systems.

For several PFAS no analytical reference standard exist

There are approximately 50-80 PFAS standards commercially available, leaving potentially thousands of PFAS with no analytical reference standard, to be identified by experienced experts, using more complex and time-consuming approaches without a reliable standard available.

Limits of Detection (LODs)

Limits of detection and quantification for tandem systems ranges from 0.5-6.5 PPB. It is important to note that recovery from samples ranges from 84-113% depending on sample preparation and other compound interference in the matrix. Inductively Coupled Plasma Mass Spectrometry (ICP-MS) is a highly sensitive and widely used analytical technique for the determination of trace elements, including Per- and Polyfluoroalkyl Substances (PFAS). The limit of detection (LOD) for PFAS using ICP-MS can vary depending on several factors, including the specific instrument, operating conditions, sample preparation method, and the specific PFAS compounds being analyzed. Typically, LODs for PFAS analysis using ICP-MS are in the low parts per trillion (ppt) to low parts per billion (ppb) range. In some cases, LODs as low as sub-ppt levels have been reported, indicating the high sensitivity of ICP-MS for PFAS determination. However, it is important to note that LODs can vary depending on the specific PFAS compounds being analyzed, as different PFAS compounds may have different ionization efficiencies and behaviors during the ionization process in the ICP-MS, which can affect their detectability.

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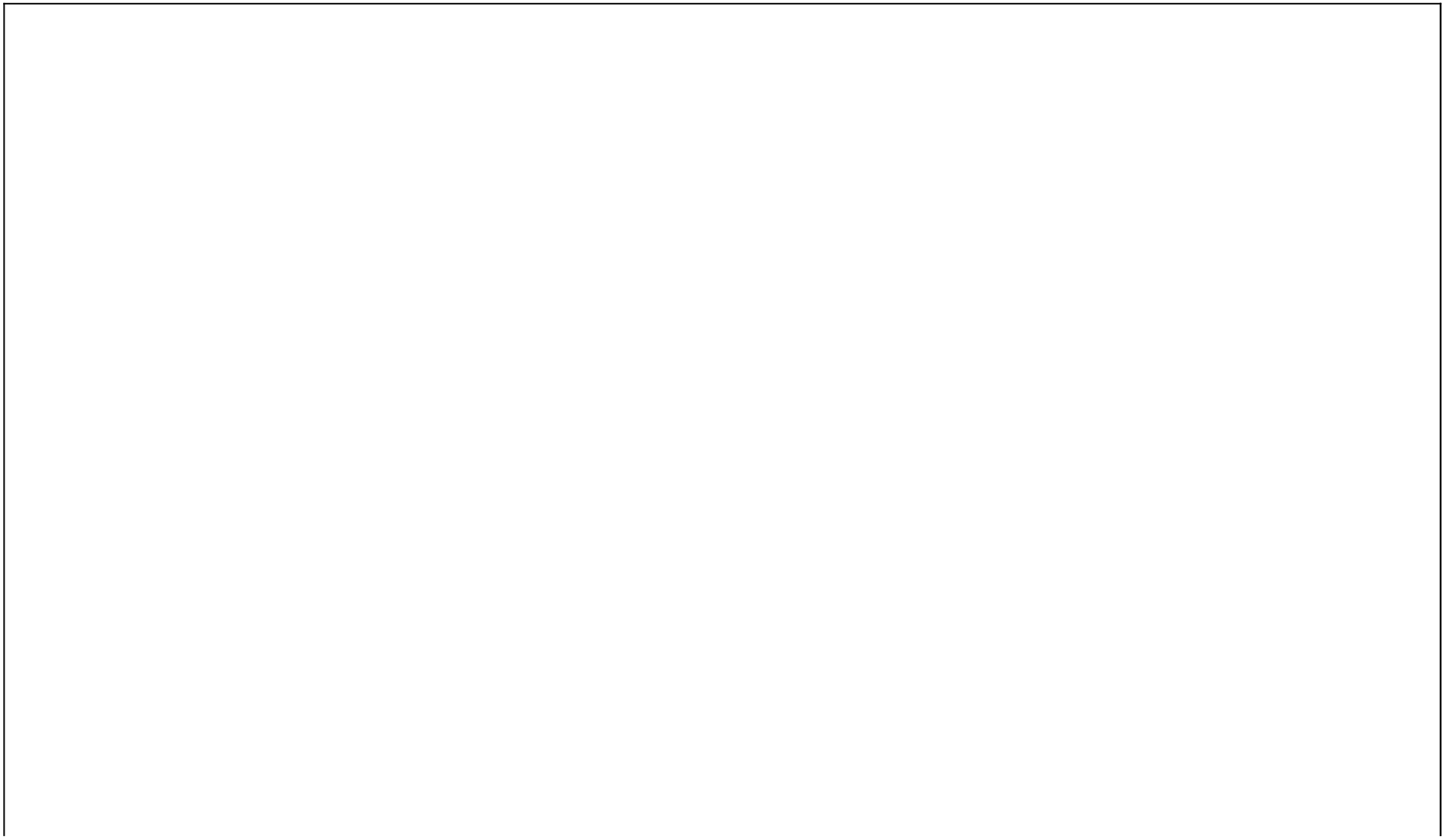

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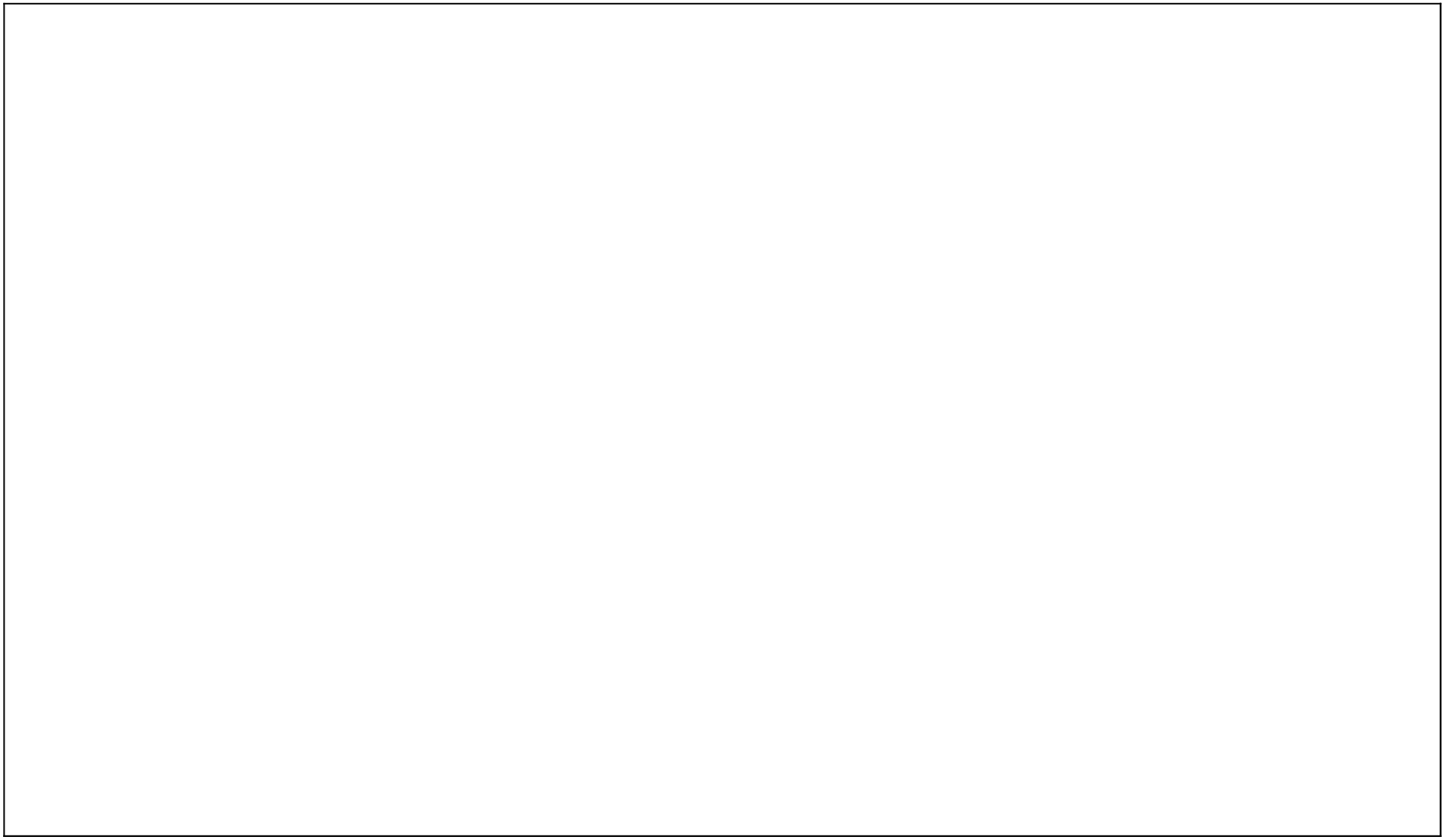
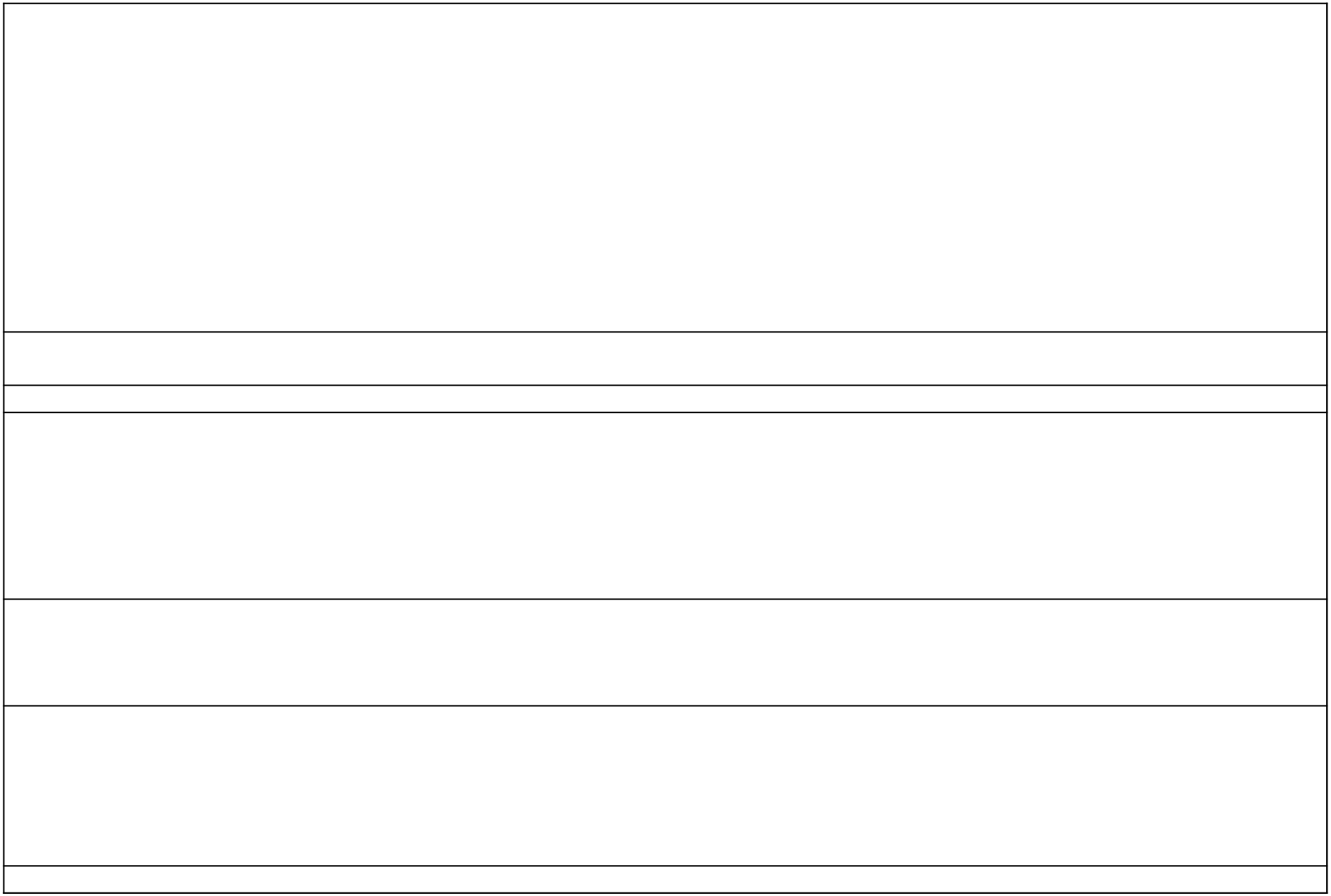
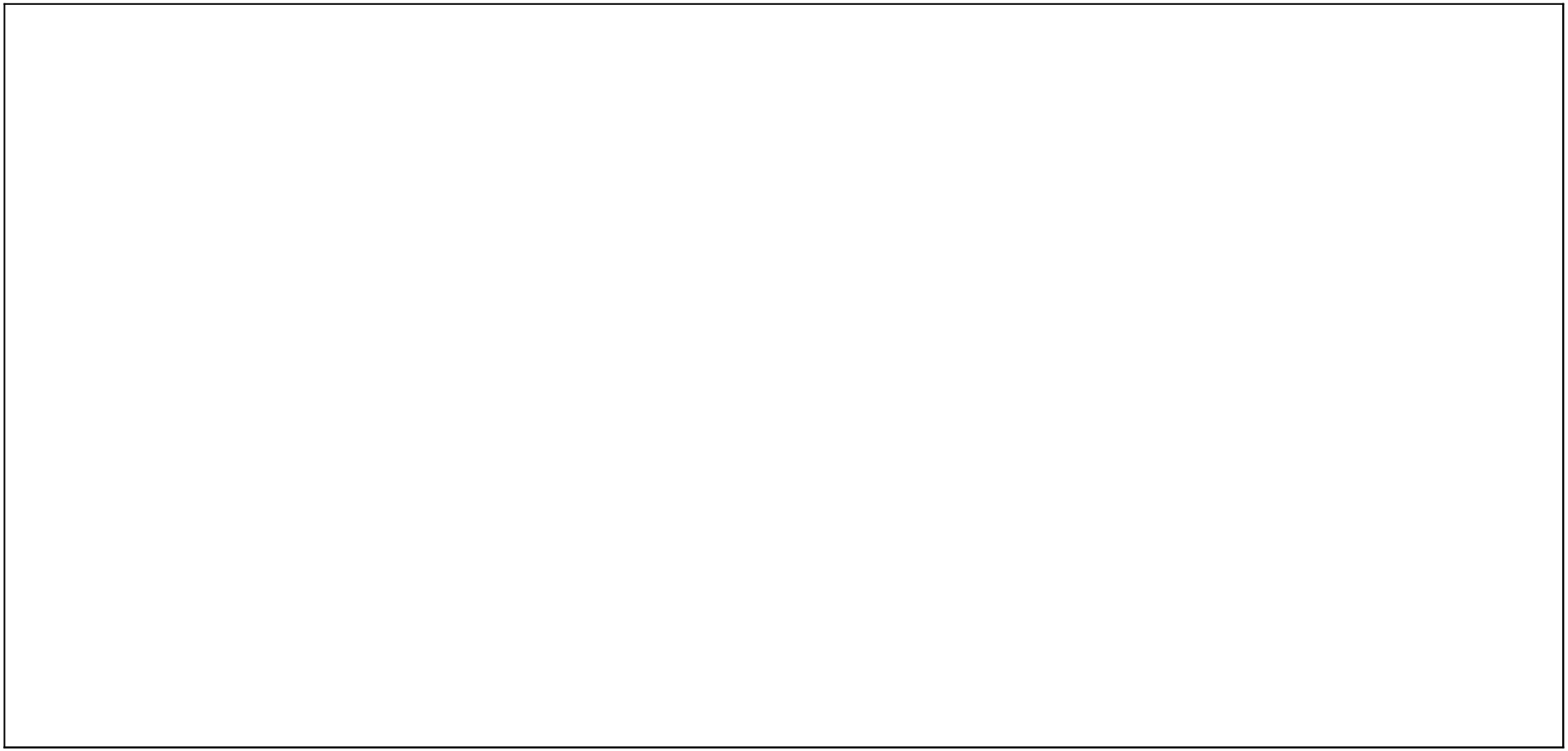




Fluoropolymers used in MD Batteries (PTFE, ETFE) are expected to exceed the 50 ppm limit. No advanced analytical methodology is needed to determine whether the 50 ppm threshold is reached.
It can be tested internally or via external lab.



Supplier tests HFIP and provides COA

Information on alternatives (e.g. are there alternatives? Are we actively looking for them? What progress is being made on finding/testing alternat
Currently, there are no alternatives that can be identified for PFAS. Further research is necessary to identify technical, economic or sustainability alternati
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No alternatives meeting economic, technical or sustainability standards:

Given the broad range of PFAS materials and uses and the variations in technical function, there is no single drop-in replacement that could be considered for instrument/device that could provide the same technical function. Several solutions will need to be identified.

There are no known alternative materials that can perform to the same standard in the majority of these applications without negatively impacting the quality of the

Previous research in to alternative materials for cost and performance has not yielded success. In fact, PFAS substances have been selected where other (non substances fail to deliver the required performance.

Examples demonstrating the dificulties in finding PFAS alternatives:

PFAS provides high hydropbicity, friction-free surfaces and provides a critical function in the fluid pathways, sample dispensing/containment of IVD instruments a

Some materials are not compatible with components which are known to cause sample reading errors in the device, due to incomplete transfer form internal extra reaction vessels. PFAS materials act to reduce the surface tension and improve the sample transfer and reading performance reducing the risk of inaccurate res repeat testing being necessary. Studies carried out on analyser sample dispensing tips showed more accurate dispensing using PFAS coated tips as comparted t coated tips. The lower surface energy of PFAS materials resulted in improved assay performance.

Timelines:

Devices that are not used in a laboratory setting, as well as certain self test devices-design of a single instrument or device would take far in excess of 13.5 years suitable alternatives were available. Studies haver also shown that PFAS materials used in seals and diaphragms results in increased durability in the field requir maintenance and potential downtime of the analysers

No suitable alternative identified yet:

Currently, no other appropriate biocompatible lubricants have been found for medical devices. Silicone-based lubricants and other thin oils pose a significant risk o
and contaminating different parts of the device. To achieve the desired thicker consistency, silicone lubricants rely on PFAS as a thickening agent.

All devices containing PFAS lubricants have been assessed through a comprehensive battery of biocompatibility tests, in alignment with ISO 10993, supporting a la
risk.

Expected timeline:

In the event a suitable alternative would be identified in the future, it would take a minimum of 3-5 years to source, assess impact to design and manufacturing pro
validate, conduct all required biocompatibility testing, update procedures, train employees, and obtain all necessary regulatory approvals for all impacted reg

No known alternatives for these applications. The properties of thermostability and Dielectric Properties are not availble in other materials.

No alternatives are known at this time, that are safe for patients, i.e., no alternatives have been assessed for impurities, and any alternatives would require full bio
and clinical assessment, as a result. Investigations into some alternatives are ongoing.

Companies report having looked into alternatives for the past several years together with suppliers. However, alternatives present challenges from technical and e
points of view. **CONFIDENTIAL INFORMATION ON THIS POINT IS AVAILABLE.**

Challenges with identifying alternatives and performance criteria for implantable medical devices:

Potential material alternatives may not maintain the same high/unique performance and associated positive clinical outcomes. It is currently unknown if potential materials will exhibit the same level of biocompatibility, advantageous cellular response, and long-term outcomes associated with fluoropolymers in invasive and medical device applications. Replacement of materials used in implantable [and invasive] medical devices is a drastically more complex and resource-intensive u than in most other applications and industries.

Conversion time and long time data:

Companeis estimate that a conversion of a single device would take approximately 20 years. Alternative materials may not effectively serve a diverse patient popu may require more surgeries, open surgeries as opposed to minimally invasive procedures, longer or more frequent hospital stays, and uknown health effects/adv that are not prevalent in fluoropolymer-containing implanted medical devices in the past 45+ years.

Biological response – especially chronic biological response – to a novel material, and the effects on long-term device performance and associated treatment outc predictable without extensive data. As previously discussed, a comprehensive suite of in vitro and in vivo (live animal) biocompatibility testing is needed/required a not necessarily be sufficient to identify all potential hazards. Years of clinical studies (i.e years of implant duration) are needed to understand the full impact of a n device performance and treatment outcomes and on human health.

Examples of materials which are hard to change:

Companies report that no viable alternative for PTFE, PFPE or ETFE have been identified despite years of research by R&D. Fundamentally no other potentially vi has the same low coefficient of friction and insulating properties as PTFE or ETFE. Any alternative that has been explored would respresent signifiant design com terms of product performance and the resulting patient outcome. Substitution of PTFE or ETFE with inferior materials will likely lead to excessive complaints in th impactful negative patient outcomes. Alternatives may also require new clinical trails and long-term studies for the stability of the leads against electrical cur

Required criteria for alternative to PTFE:

Alternatives to PTFE may face challenges with liquid sterilant solution, autoclave, and ethylene oxide sterilization. PTFE alternatives may have less effective surfa undesired interactions. In the event an alternative becomes technically feasible, there are substantially fewer providers of alternative material than PTFE materials the current market. This would put a substantial restriction on the supply chain for essential life-saving devices.

Alternative lubricants may not be biocompatible and/or promote ethylene oxide gas exposure sufficiently.

CONFIDENTIAL INFORMATION ON PVDF AVAILABLE.

Consequences after identification and validation of an alternative:

There would be significant expenditure required to eliminate PTFE coatings from all products immediately given that many jurisdictions will require regulatory subm can take up to 2 years after a company has provided equivalency data as well as packaging changes. There will also be significant retooling required both at faci supplier facilities to enable the transition. The newer generation products (PTFE coating free) are fundamentally different from the legacy products meaning hea

Alternative materials to PTFE for catheter applications were assessed for feasibility. Criteria used for the evaluation included mechanical properties, friction adhesion/cohesion testing. Of ten materials evaluated, only one non-PFAS material was deemed viable for lubricity but deemed to be deficient in other engineering Therefore, the risk for transferring device designs to this alternate material is significant.
Device functionality would likely require larger diameters to accommodate frictional resistance which would lead to larger insertion diameters for minimally invasive would have significant adverse consequences for patients.

Catheter Liners:

Alternatives for catheter liners are available; however, they are critically dependent on the device application and not universally replaceable. The requirement for lo of friction, mechanical properties, sterilization, and assembly are all examples of criteria that must be considered since form and function of the device is impacted. certain manufacturing processes are dependent on PFAS products such as FEP. FEP is often used in heat-shrinkable tubing that reduces in diameter when expos source. This then defines the outside diameter of a catheter during manufacturing. This FEP shrink tubing also prevents the adherence of the shrink tube itself to t material, allowing it to then be “peeled” away after the assembly step. No non-PFAS material has been identified and successfully implemented at this tim

Guidewire coating:

Uncoated guidewires are technically feasible, but have a higher risk of patient harm. Coating guidewires allows for their smooth insertion into the vasculature. W coating, clinicians may confuse the wire sticking to the vessel for a larger, more critical vessel blockage and not be able to differentiate the severity of the issue. Gu “stick” to the vasculature can cause thrombogenesis and patient harm. Uncoated guidewires make up a small portion of the offering of those that are commercially the EU.

Timelines for identification of alternatives

Efforts to find and procure a suitable alternatives, assess impact to design and manufacturing process, procure and qualify additional equipment, re-validate proces all required biocompatibility testing, update procedures, train employees, and obtain all necessary regulatory approvals for all impacted regions would require a mi years. Additional redesign, testing and approval time for devices which are used together for the procedure could require significant additional time and reso

Technical performance properties of fluoropolymers and challenges with alternatives

Fluoropolymer such as PTFE has the third-lowest friction coefficient at 0.05 to 0.10 of any known solid material (aluminum magnesium boride being the first, with a friction of 0.02; diamond-like carbon being second-lowest at 0.05). (https://en.wikipedia.org/wiki/Polytetrafluoroethylene). Both aluminum magnesium boride and c carbonare are inorganic materials and don't have sufficient flexibility, a design requirement for interventional devices. No alternatives for in-use fluoropolymers exis meet product, material, function, performance, and patient safety requirements. This is based on the intrinsic properties of in-use fluoropolymers, including lubricit introduction forces, flexibility, and replacement material evaluations and feasibility. No other materials meet the same requirements such that they would be s replacements, without significant product performance, patient safety, or socio-economic risks. PTFE coating was selected for its low coefficient of frictio

Experience in alternative assessments:

At the current time, there is no alternative that can achieve the same properties. Alternatives have been evaluated multiple times over the past 10 years. In eac suitable replacement that could maintain the friction performance could not be found. The performance evaluation included direct friction measurements as well

No research or no known alternatives (proven to be acceptable from a patient safety). Some companies indicate that it would take up to 10 years to find and va
alternative to a PFAS-containing material

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These devices and their percutaneous delivery rely upon low coefficients of friction to function correctly. Incorrect function generally leads to device non-deployme
deployments. The sheaths delivery system components must slide relative to each other to perform their functions. Alternatives could require lubricating the dev
use, or the addition of some other hydrophilic coating, but would require investigation if these alternative materials or designs would function the same as the curr
Some companies indicate that it would take 5-10 years to identify, develop and validate an alternative to a PFAS-containing material

PFAS properties and challenges with alternatives

PFAS provides excellent dielectric strength through PTFE, which is key to the cardiac signals and ablation energy wires as these are higher gauge wires in close each other. The thermocouple wires also don't have good options in this use case. These thermocouples must be flexible or they won't be manufacturable inside generator, must be small in diameter since the connectors are high density (SS and fiberglass have larger jackets) and must be durable (fiberglass can easily fra cause dielectric issues next to cardiac signals). A suitable alternative, that has the combination of a low coefficient of friction, electrical isolation, thermal stability, strength, and biocompatibility has yet to be identified. The use of fluoropolymers in these medical devices enables the device design to meet product, performance requirements. A forced introduction of non-FP materials in place of FP ones presents the potential for significant product performance, patient safety, and socio- risks.See friction coefficient data on PTFE in previous section. At the current time, there is no alternative that can achieve the same properties. Alternatives such a on the proximal end of the guidewire have been evaluated multiple times over the past 10 years. In each case a suitable replacement that could maintain the performance of PTFE could not be found uinless it is another PFAS. The performance evaluation included direct friction measurements as well as in-vitro bench te the alternative materials demonstrated inferior performance relative to PTFE coated controls. No alternatives for in-use fluoropolymers exist that would meet produ function, performance, and patient safety requirements. This is based on the intrinsic properties of in-use fluoropolymers, including lubricity, strength, introductio flexibility, and replacement material evaluations and feasibility. Guidewires, cannulas, syringes, need fluropolymer coatings to provide lubricity allowing them to m each other inside cables, handles, etc. allowing for flexible cables providing ease of use of the product as well as extending the lifetime of the device without issue friction. Coating the wires is also required to make manufacturing feasible for reducing insertion stress on wires placed into narrow shafts as well as being therma high reflow temperatures required in manufacturing.

Engineering polymers (i.e. blends of polymers, compounded together) may offer potential replacement for certain PFAS based applications, but generally there ar available alternatives, and any suggested alternatives would likley need to be qualified and validated for use in a medical device application, due to the potential im alternative polymers may introduce, which then requires new biocompatibility and clinical evaluaiton, all of which requires several years to assess, not to mention, are successful, several more years to develop and qualify the associated manufacturing process (even a seemlingly simple change in polymer composition of one can then impact how the product is made, since the new polymer may require different temperatures and compressive forces, which then require retooling and new to accommodate), not to mention the additional time required to then undergo Notified Body conformity assessment against the General Safety and Performance R under EU MDR, needed to obtain CE marking.

Fluorinated release liners are used in these applications for their very specific release properties, chemical & heat stability as well as affinity to formulations in transdermal drug delivery. Interaction between the drug and the release liner is frequent. Fluorinated release liners bring unique properties and stability in such situ release liners such as PVC, Polyethylene have been tested as alternative to Fluoropolymers coated liners without success. Currently, there are no straightforward that meet the requested properties.

Examples of avaiable alternatives, however not suitable

A member reports that although non coated stoppers alternatives are today available, these are not suitable for highly sensitive medicines. For these sensitive me PFAS coating plays a key role by providing a barrier effect against extractables, minimizing the risk of interaction between the container and the drug during its sh

No known alternatives (proven to be acceptable from a patient safety)

Opthalmic lenses, such as the Intra Ocular Lenses (IOL) used in cataract surgery, are used to replace the natural (but clouded) lens of the eye in cataract patien already undergoing a substitution project, with first release of a non-PFAS lens expected in 2028. Unfortuantely, there are literally hundreds of different IOLs (ea unique shape and power, to accommodate the varying visual defects of each individual patient), and it will likely take many more years, to fully replace all of these with a non-PFAS alternative lens formula, since each type of IOL (i.e. each unique shape and power, monofocal, multi-focal, etc., etc.) must undergo its separate c work, including clinical trials and efficacy testing

No known alternatives (proven to be acceptable from a patient safety).

Reason for use

Chemical resistance, Temperature resistance, humidity resistance, inertness, barrier properties. The PCTFE in the packaging provides hydrophobic properties maintaining the product moisture-free during it's shelf life. It is present as a thin layer laminated onto the packaging.

Research ongoing

Alternatives are being researched but no drop-in replacement has yet been identified. Even if an alternative was identified, changes would be required to be made and fill lines and an additional 10 years is estimated to complete.

Unfortuantely, there are literally hundreds of different IOLs (each with a unique shape and power, to accommodate the varying visual defects of each individual pa will likely take many more years, to fully replace all of these iterations, with a non-PFAS alternative lens formula, since each type of IOL (i.e. each unique shape a monofocal, multi-focal, etc., etc.) must undergo its separate development work, including clinical trials and efficacy testing

Known alternatives

Known alterantives to PCTFE include laminates of PVC/PVDC, or polypropylene-cyclicolefin copolymer, but these materials would need to be tested for biocompa new impurities are introduced (likely given a material change such as this), then new risk assessments, clinical evaluation and efficacy testing will be required o material, so even if a new material such as PVC/PVDC exists in theory, it is unproven in practice. At times, manufacturers and suppliers of such materials even refu the material for medical device use, given the potential impurities that it may introduce, so again, these alternatives are very much a priori

No known alternatives (proven to be acceptable from a patient safety),research being made

A company been actively seeking an alternative to the PTFE membrane used in certain contact lens disinfectant products. Their existing PTFE membrane sup
suggested two potential replacements. Both materials have been tested by the supplier for crtitical-to-quality attributes. Unfortunately, they will either not adhere t
cap component of the product, which the vent membrane must be sealed to), or may lead to other environmental concerns).

Investigating alternatives for packaging of terminally sterilized devices. Whether by autoclave, ETO, or low temperature vaporized hydrogen peroxide, there are alternative packaging alternatives acceptable from a patient safety perspective.

Extensive efforts have been made to substantiate the safety and efficacy of the current use of PTFE within validated processes and approved products. Therefore, active efforts to pursue material alternatives at this time.

Efforts to find and procure a suitable alternative, assess impact to design and manufacturing process, procure and qualify additional equipment, re-validate proces all required biocompatibility testing, update procedures, train employees, and obtain all necessary regulatory approvals for all impacted regions would require a mi years.

The assessment of alternatives can require different amount of years, based on the different uses and technologies available:

Alternatives may exist, but are generally a priori, and would need to be proven (i.e., qualified, then design verifiied and validated, and if the packaging impac form/fit/function of the device itself, then additional biocompatibility and clinical evaluation would be necessary, followed by Notified Body conformity assessmer General Safety and Performance Requirments of EU MDR (for human health requirements), in order to obtain the CE mark necessary to place the device on the note that even packaging is sometimes regulated as part of the device, in particular primary packaging. In total, all of this activity could take up to 12 years in a v scenario, where the primary packaging material change impacts form/fit/function of the device, requiring the train of data needed to reintroduce the device without of particular concern in cases where no PFAS is readily known AND in purity or grade that is sufficient for use in medical devices, which then may require years o ideation and discovery, apart from our own stringent development requirements.

Potential alternatives to PTFE have been found to reduce cable flexibility impacting durability and ergonomic usability issues. In the event a suitable alternative
identified in the future, it would take a minimum of 5-10 years to source, assess impact to design and manufacturing processes, re-validate, conduct all required bio
testing, update procedures, train employees, and obtain all necessary regulatory approvals for all impacted regions.

Potential alternatives to FEP materials have been evaluated but failed to meet required properties and technical specifications for safe and effective use, includin
electrical insulation requirements. Since no viable alternatives are available, a complete redesign of devices would be required. A timeline of 10-15 years consist
Development (5-10 years) plus testing with full regulatory certification and approval would be needed.

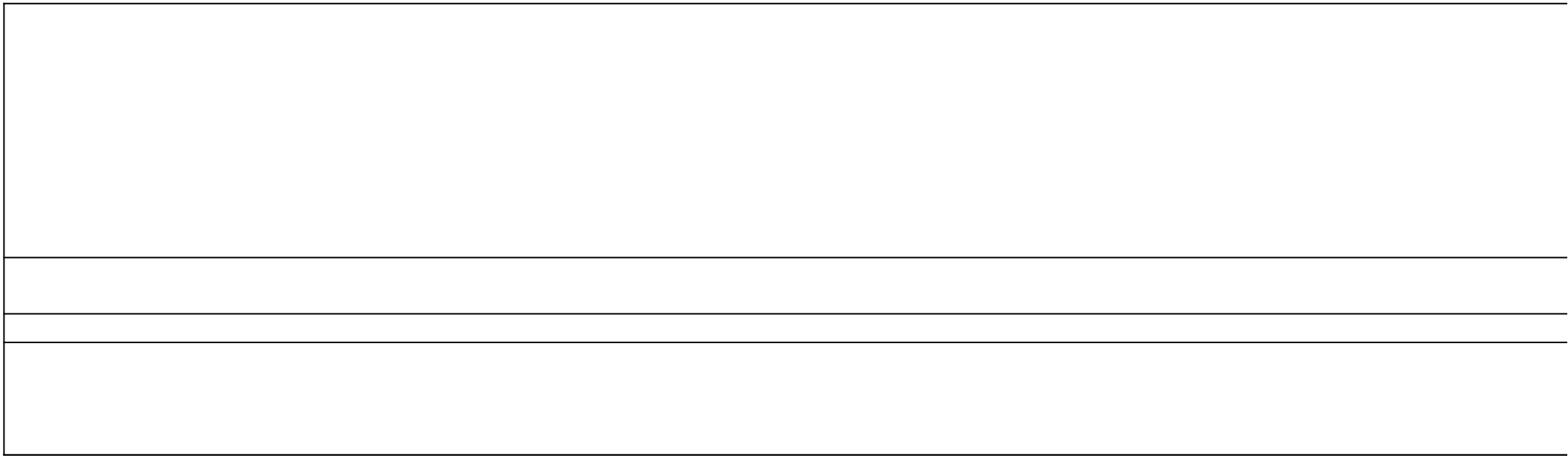
For blood glucose meters and test strips, since up until now, the risk of the usage of PFAS was never addressed, the use of PFAS in PCBs and the like is so wides
is nearly impossible to find electric components without PFAS.
No suitable alternatives have been identified yet and additionally it takes a long time for material changes due verification/validation as well as registratio

There are two main considerations for the impact of any alternative packaging material changes for regulated medical devices: **Biocompatibility**: Any changes to primary barrier packaging materials would require an extensive re-validation of required clinical endpoints, after aging, to rep useful life of the device. **Sterilization**: The impact of changes to primary sterile barrier packaging design or materials for medical devices would trigger industry-wide verification and validat For example, many products within industry rely on ethylene oxide (EtO) as a common mode of sterilization. In this case, the primary sterile barrier packaging is designed to allow proper sterilant gas penetration. This is not only important to achieve sterility assurance levels, but also to allow for proper degassing of the st biocompatibility purposes. The ability to assess the impact of packaging changes on sterilization validations would be substantially restricted to the sterilization capacity to support such an industry wide change while trying to maintain the capacity to sterilize devices for current patient demand. In the event a suitable alternative would be identified in the future, efforts to procure, conduct necessary packaging validations, conduct required biocompatibility obtain all necessary regulatory approvals for all impacted regions would require a minimum of 10 years.
The lubricity of fluormaterials is needed for certain applications of molding thermoset materials. No alternatives are known at this time but may be possible. Al polymeric materials may be possible but it has not been studies.Without a mold release of similar lubricity certain types of thermoset parts can not be manufacture low risk application with requirements of significant work to develop, test, and quality a new process or material.
Alternatives - for one specific example, a dozen alternatives, including polyoxymethylene, EPDM, PVCs, and several different fluorinated polymers were evalua fluorinated polymers performed the best, although with higher operational costs since the materials are consumables on the production line.

No alternate for out-patient procedure. For interoperative application, the alternative at this time is silicone oil for use as a tamponade in place of fluorinated gas. However, use of silicone oil requires a se for removal, significantly increasing patient recovery time and chance of complication, including recurrence of detachment (McCabe et. al., 2019). Thus, there is surgery alternative substance available at this time.
Due to its nature and chemical as well as friction properties, PFAS containing material was chosen in the development of the device. Since it was aimed to put a product on the market, it was necessary to ensure that the functionality does not decline with each use. The use of a less resilient material may decrease the long product and thus produce more contaminated waste. No suitable alternatives have been identified yet and additionally it takes a long time for material chang verification/validation as well as registration.

Long timelines will be needed to implement the alternative due to many multiple-year steps to be completed; such as redesign of the pen injector, functional per testing to ensure that the alternative lubricant will remain stable during the (up to 5 years) shelf life of the pen injector and extensive regulatory approval from the d well as from the drug side to ensure maintained functionality of the pen injector.

Fluoropolymers serve multiple purposes in the batteries of implantable medical devices. A forced removal of fluoropolymers for battery manufacturing would require a complete redesign of the battery and could potentially compromise the functionality life of the device.
There are no currently available known alternatives, these can be evaluated through R&D. Once an alternative would be identified for the Ink formulation, qualific alternative would be required for the mentioned application. Alternative may trigger process changes at multiple manufacturing sites across multiple locations and due to the variety of sophisticated high-volume manufacturi signficant process development is anticipated after the formulation is finalized and passes all the biocompatibility testings increasing the substitution timeli
No known alternatives



No suitable alternatives have been identified that would result in equivalent device performance and usability.

In the event a suitable alternative would be identified in the future, it would take a minimum of 3-5 years to source, assess impact to design and manufacturing pro
validate, conduct all required biocompatibility testing, update procedures, train employees, and obtain all necessary regulatory approvals for all impacted reg

No known alternatives for these applications.
The properties of thermostability, Lubricity, Dielectric Properties, biological Resistance/ Sterilization and Biocompatability are not available in other produc

b. PTFE used for suture: The nonabsorbable monofilament sutures on the market consist of PTFE, nylon, and polypropylene. Sutures made from PTFE are far s
terms of patient comfort due to the softness of PTFE in contrast with harder surfaces of nylon and polypropylene. The element of patient comfort is of increased im
dental applications due to the heightened sensitivity of soft tissue in the mouth.

Currently in the process of minimizing the solvent use by mixing non-fluoro solvent with HFIP and utilizing smaller size GPC columns. However, at the current time, be eliminated completely and therefore derogation is necessary.

Information on costs
Depending on the alternatives developed/available, it could cause the cost of our products to increase.There will be an additional cost to recover redevelopment costs.

Risks:
Especially for vertical movement above the samples such non greased axis are essential. Instrument downtime for service or exchange would increase cost and waste. A single clinical laboratory IVD instrument could contain multiple components containing PFAS materials. Re-design and substitution costs would reach millions.

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CONFIDENTIAL DATA AVAILABLE; costs are estimated to be upwards of tens of millions.

Negative impacts to patients in case PFAS is restricted:

Without a feasible alternative, patients may not readily have access to these procedures, and could require additional hospital stays and other risks as previously described. The costs would be significantly higher if some patients were to incur more severe morbidity impacts. Open surgical procedures often include longer hospital stays, which typically correspond with:

•Additional risk of infection (often corresponds with higher morbidity)

•Increased procedural time (often corresponds with increased length of exposure to anesthesia)

•Increased hospital stay length (often corresponds with higher healthcare practitioner burden, higher risk of infection or reintervention, increased emotional/mental health impacts, and significantly increased financial cost of treatment)

Some medical devices treat especially vulnerable patient populations, including babies and terminal cancer patients. Patient populations such as these often require highly specialized and sensitive care to minimize complications, ensure fewer procedures, and generally improve quality of life.

Costs to medical sector:

Increased resource costs annually to medical practitioners from additional surgery time and familiarisation time to use different medical equipment and/or devices. With potentially longer hospital stays, hospitals will not be able to treat as many patients annually. It is reasonable to assume that a reduction in total patients treated would result in a loss of income to the hospital. This would also be the case should alternate treatments not be available. Both longer hospital stays and lack of alternative treatments would likely limit hospitals' ability to treat and operate at current volumes. Less patients may also equate to less hiring of hospital staff, doctors, nurses, etc.

Limited R&D Resources:

R&D would be re-focused on seeking alternatives and validating replacement products (to serve the same patient populations) instead of creating novel or improved products for existing and potentially new patient populations. R&D will already be seeking alternatives for other chemicals under current scrutiny by REACH (e.g. bisphenols, microplastics, PVC).

Costs for manufacturing adjustments:

Additionally, alternative non-fluorinated materials will likely require completely novel equipment and tooling in order to produce, both in limited amounts and at scale. This would remain consistent throughout raw material manufacture all the way through device construction, requiring highly modified manufacturing areas, fixtures, and training of staff.

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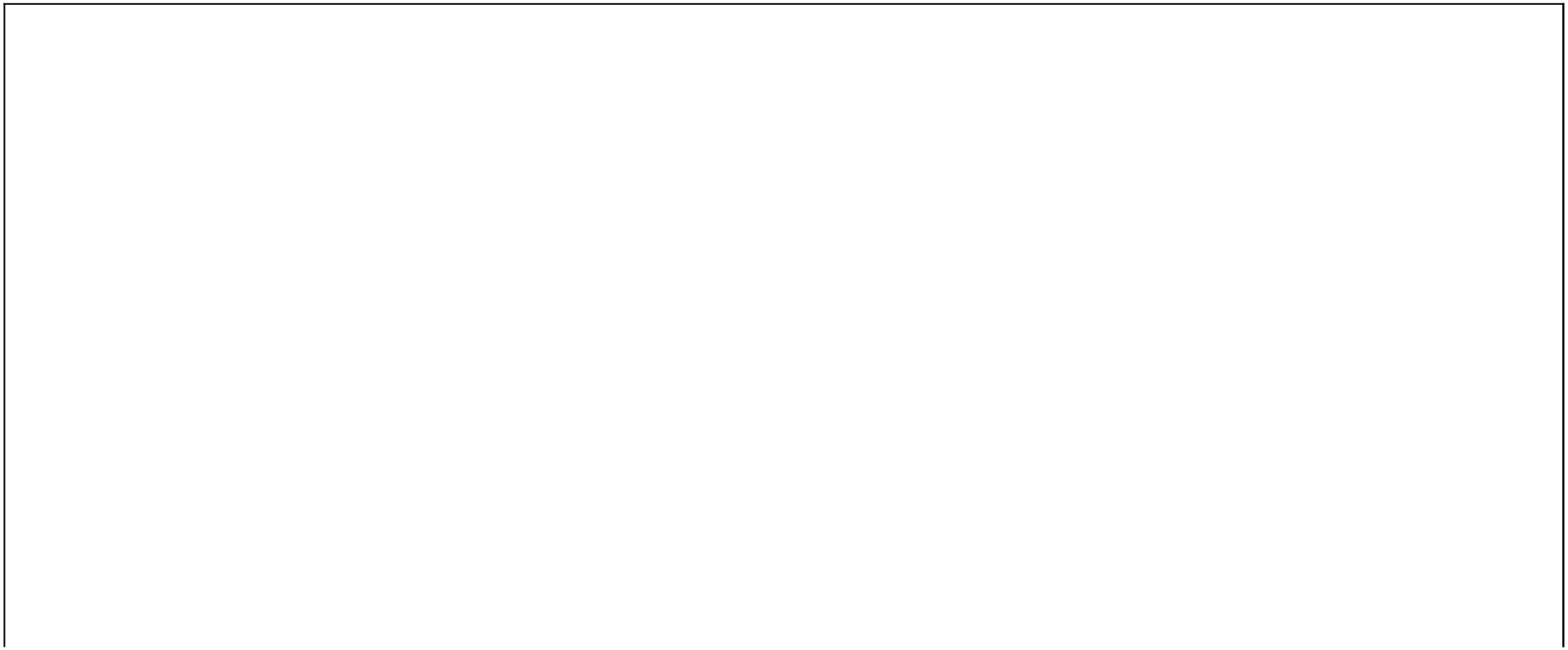


Negative impacts to patients in case PFAS is restricted

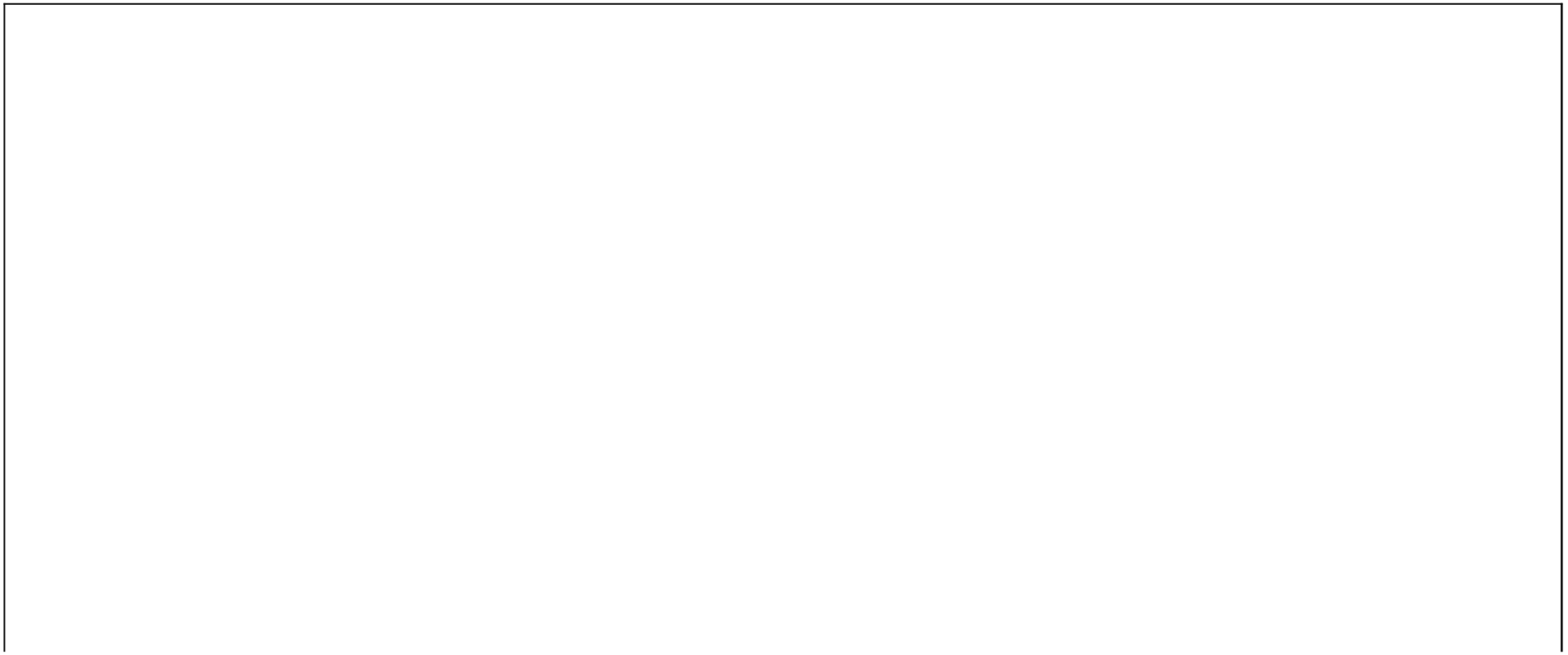
A member report that with a no derogation scenario the impact will be high in Europe at first for patients and society but also for industry.
No derogation will result of drug shortage of key medicines on the european market. We estimate that more that 200 Biologic Drugs are placed on the European Market each year in prefilled syringes and due to their sensitive nature, PFAS coated stoppers are used.
Examples of indications of these drugs include but are not limited to multiple sclerosis, rheumatoid arthritis, and neutropenia.
No derogation will also have a high impact on innovation and future new drugs launch on the European Market. We estimate that there are approximately 100+ biologic drugs in clinical trials across the European Union that are expected to be launched in a prefilled syringe device with PFAS coated stoppers.

Cost for finding alternatives:

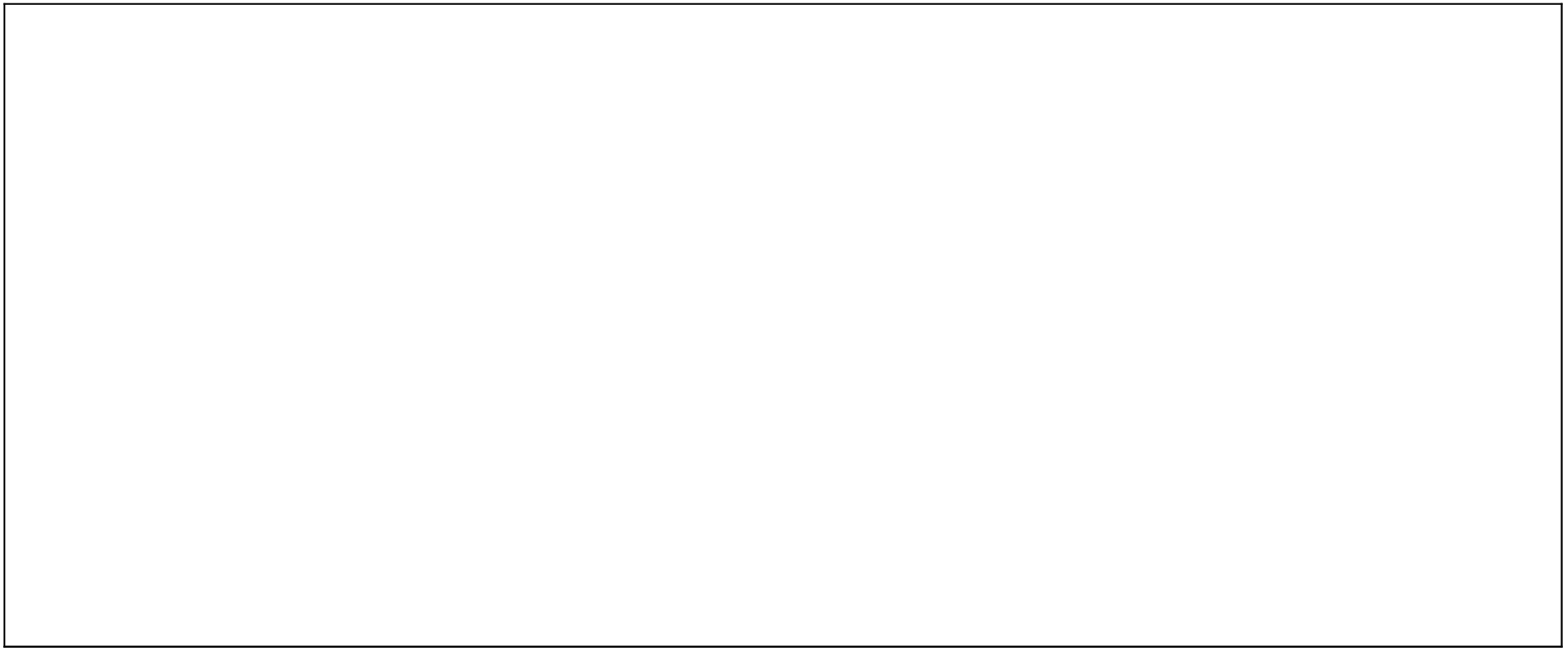
Alternatives would need to be developed, along with processing equipment. There will also be a required clinical trial, especially considering the invasive nature of the medical devices. Estimated substitution timeline is 6 years for technology development (including clinical trial) & 2 years for process development & approx 5 years for implementation to manufacturing plants, due to problems identified & requiring solving with high speed, high volume manufacturing. **CONFIDENTIAL INFORMATION AVAILABLE**

Costs for manufacturing adjustments:

For industry it will have a high impact as coated stoppers are partly manufactured in Europe and Drug filling is also done in Europe.
Transformation of this supply capacity will require significant time and investments as all manufacturing equipments will have to be converted to produce PFAS free stoppers, this includes rubber stopper manufacturers and pharmaceutical filling lines that will have to be updated.



While PFAS-free alternatives for laminated packaging are known moving to an alternative material would result in changes to packaging and filling lines resulting is significant costs.



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For PTFE example, the impact of validating and acheiving an alternate material approved for use with the rigor of electrical safety testing would cost **CONFIDENTIAL DATA ON COSTS AND PATIENTS IMPACTED AVAILABLE.**

For blood glucose meters and test strips: many home-use self-analysers, such as the blood glucose meters (BGMs) are designed as affordable appliances. Alternative materials (eg. PCBs), since they are quite rare, can be very cost intensive, and together with lengthy design change and development periods - increase the cost of manufacturing immensely. This will make the distribution of affordable medical devices for all patients even harder.

Changes to packaging materials would impact all sterilized medical devices. A limited set of expertise and resources in this area would strain sterilization providers, necessary product changes and regulatory submissions for the entire industry. The cost of validating and achieving an alternate packaging material approved for use would be significant and not economically feasible. Millions of patients in the EU could be potentially impacted if there is no derogation for use.
As identified in Annex A of the restriction, section A.3.10.1.14, "Trifluoroacetic acid (TFA) is used in analytical and production processes. It is an additive to the mobile phase in high-performance liquid chromatography applications. There are also many ingredients that are used as TFA salt." this is an example of the use of PFAS that are used in reagent products. However, only trace levels remain in the finished IVD, higher concentration exist in the production process. As this is considered the industry standard. Removing Fluoro solvents from this process for all of the impacted products would require multiple steps for each impacted product.
It would limit options for manufacturing of these products in Europe

The global pen market is 1.2 billion units and growing at 2-3% over the next 5 years. These products are used for delivery of insulin, GLP-1 (targeting diabetes and obesity), growth hormone drugs, fertility drugs, and osteoporosis drugs to patients as daily use, life-sustaining measures. For diabetes and obesity, pens make up 56-83% injectable units sold and are embedded in the way healthcare practitioners educate and train their patients to self-administer these medications.

Patients' health will be directly impacted if there are no printing available on the medical devices which is critical for the functionality of the product. If essential printing is removed from the medical devices and from the device part of an integral drug-device combination for critical attributes then it will add more chances of errors resulting in prolonged time of treatment of the patient due complexities. Loss of this will result in high risk outcomes.

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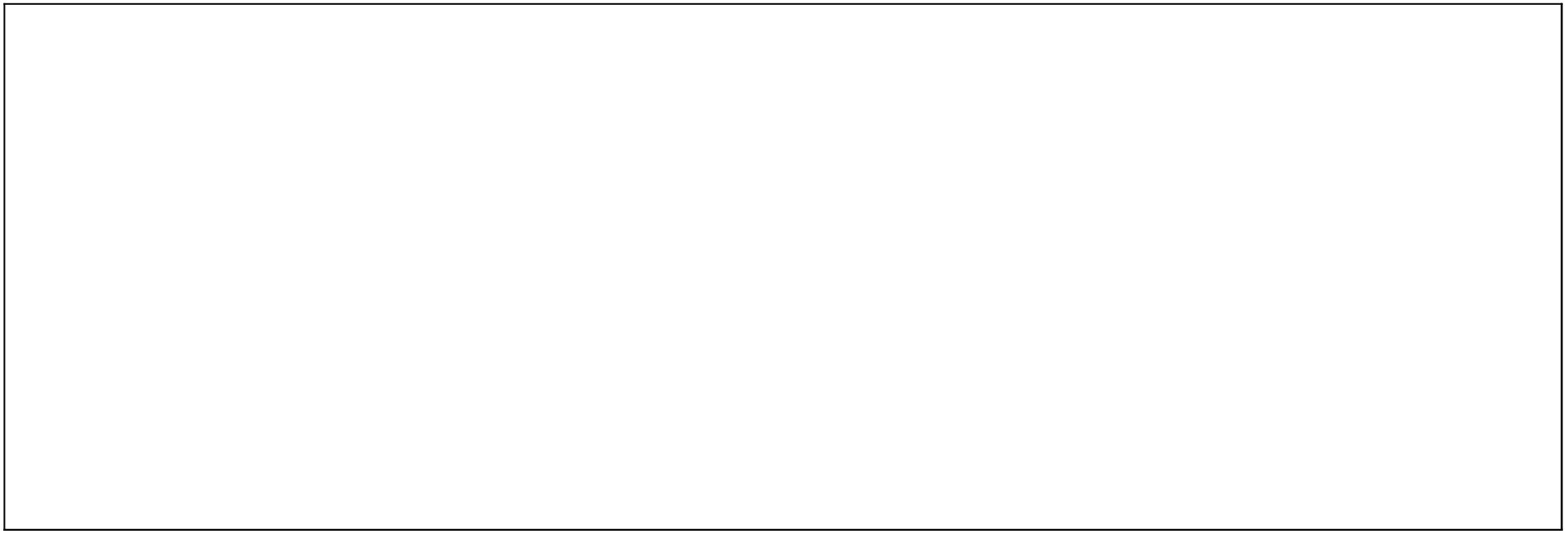

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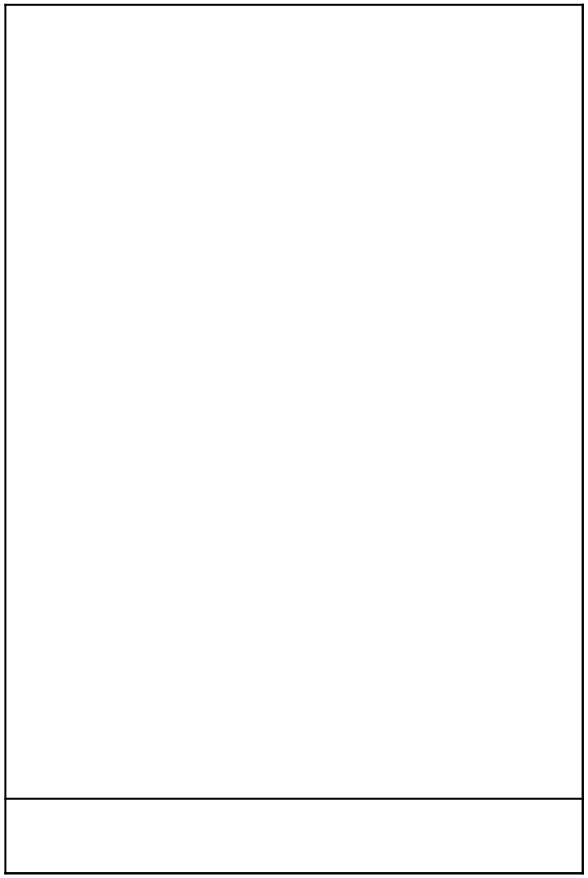
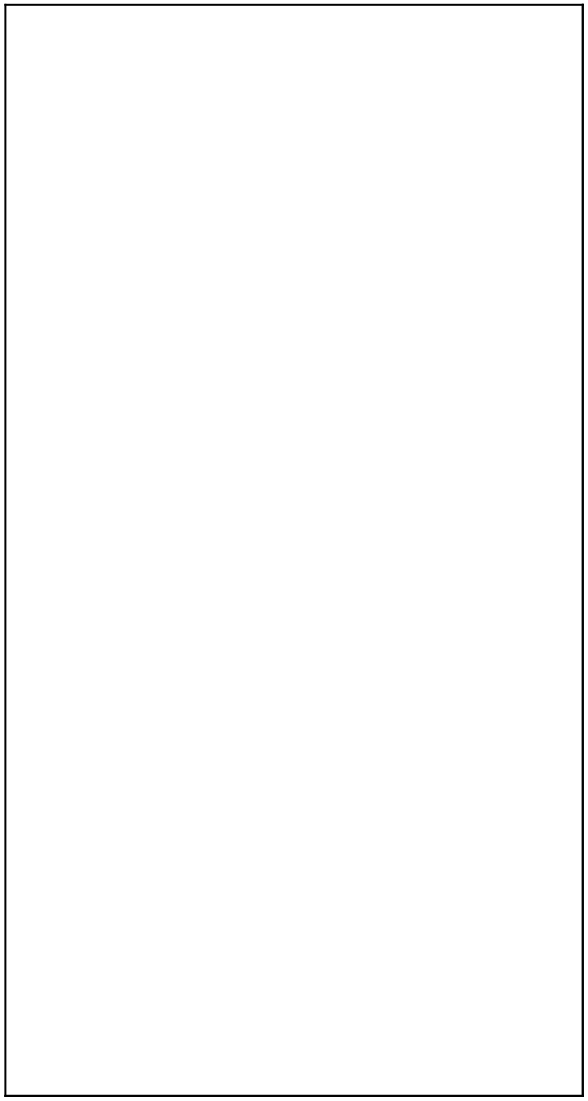
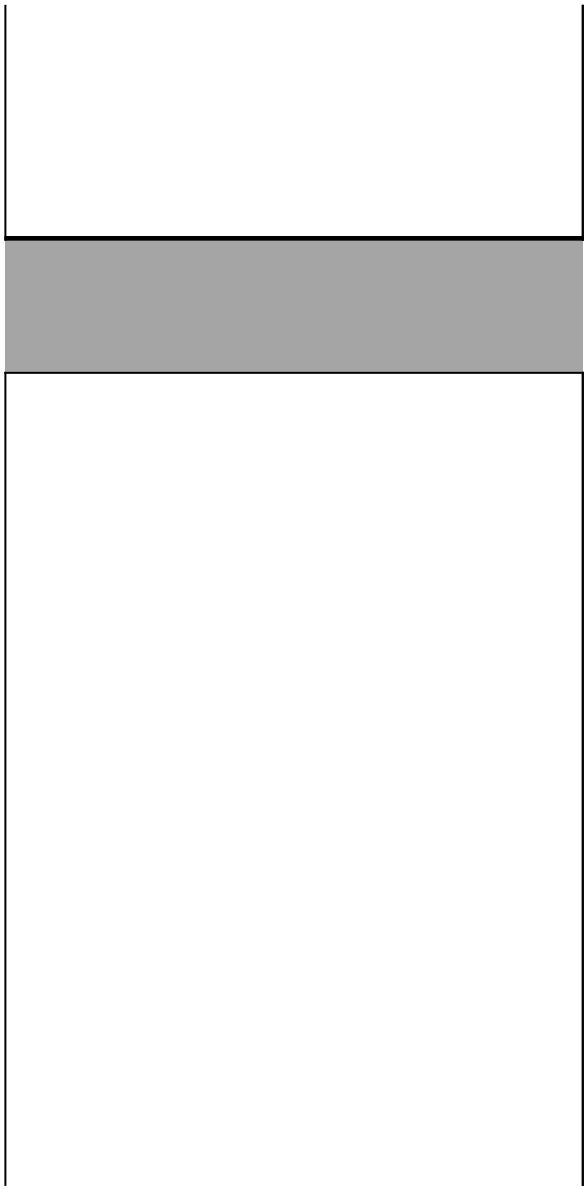
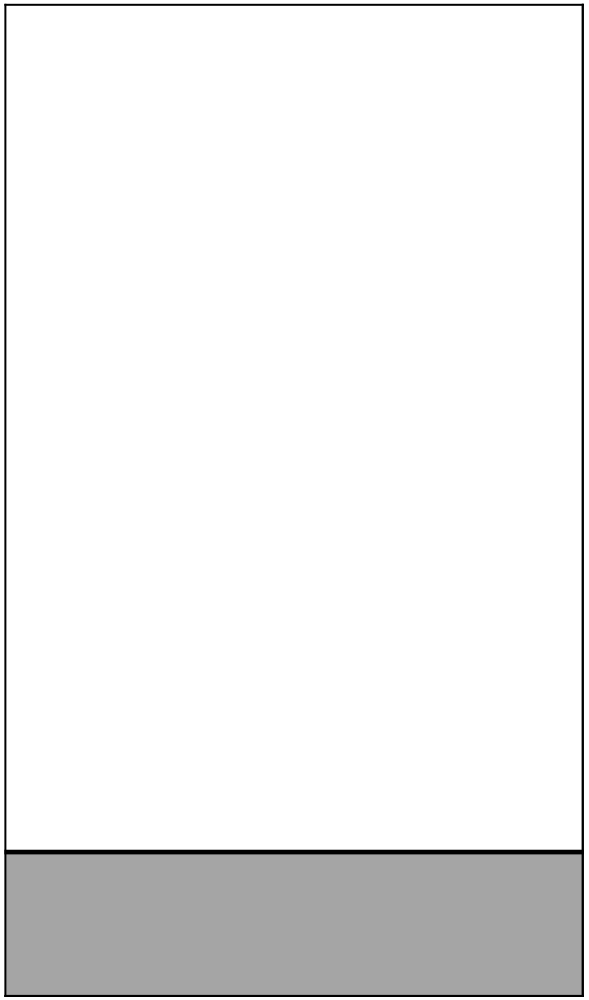
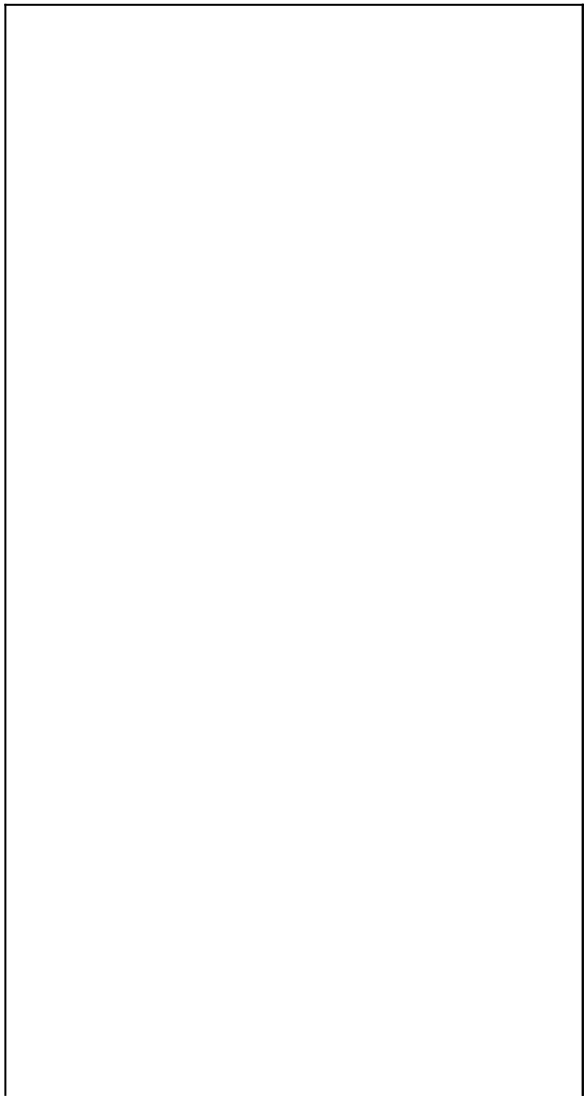




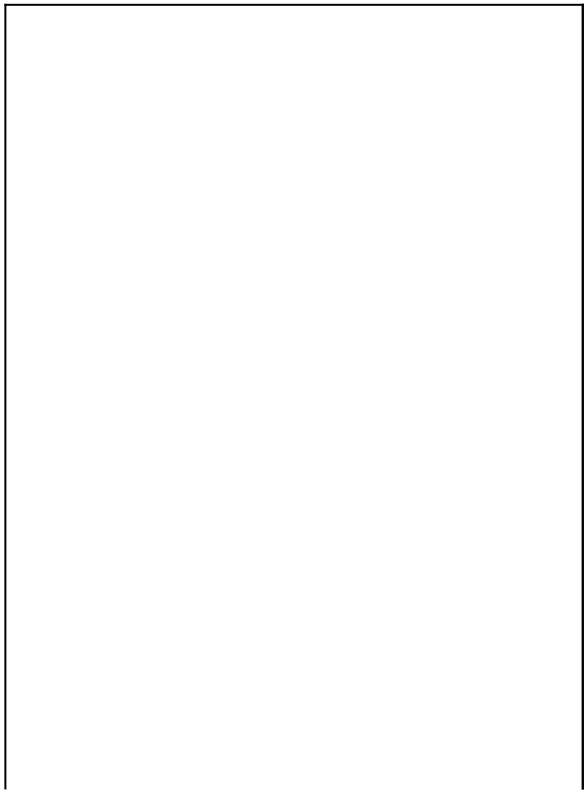




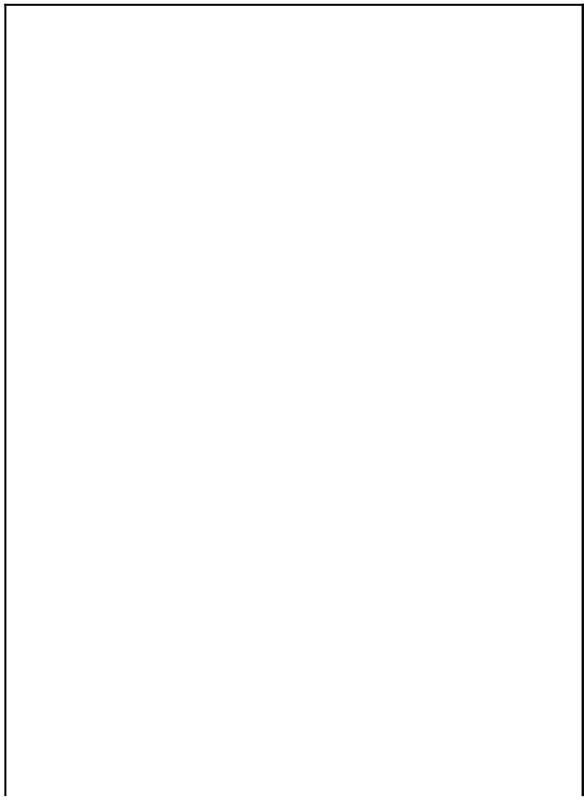


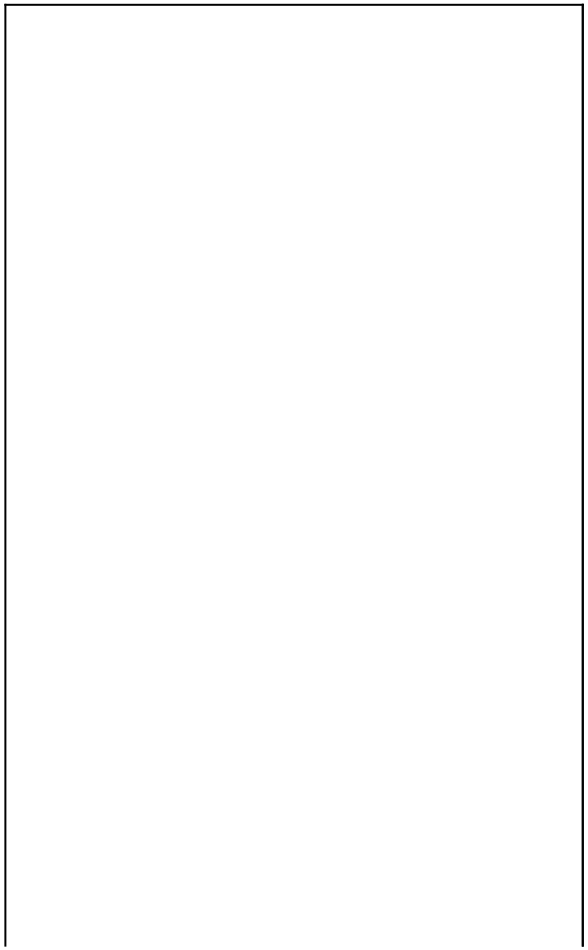
No benefits expected for industry.
It can be expected that the innovation and development of medical devices will be transferred to countries outside the EU, with the proposed production and marketing limits in the EU the ban will impact European medical device industries in the future. The society, especially patients, will suffer from old medical devices which cause more pain during medical procedures as with new innovative medical devices.

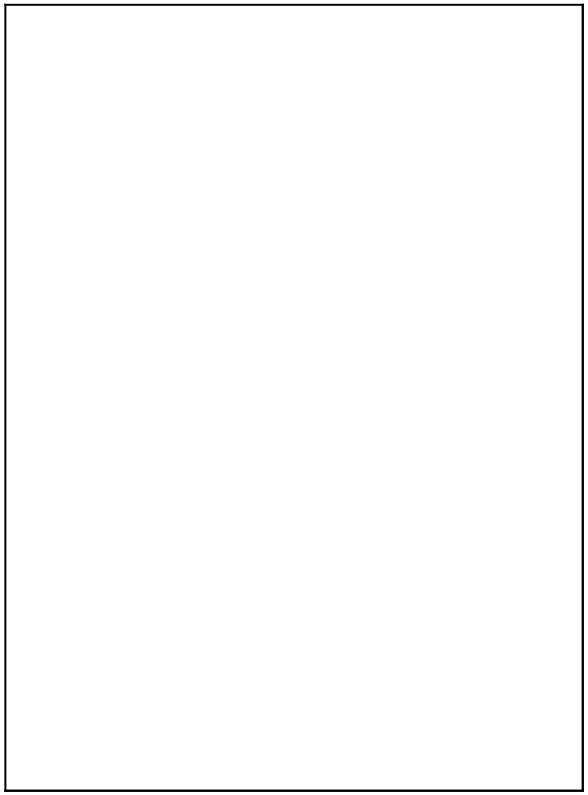
No benefit to the business.

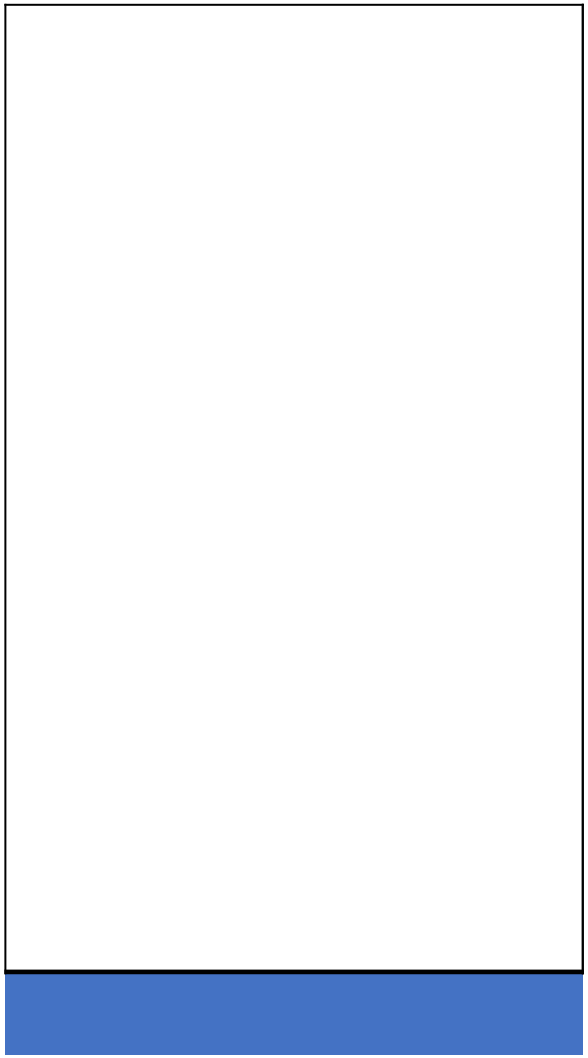


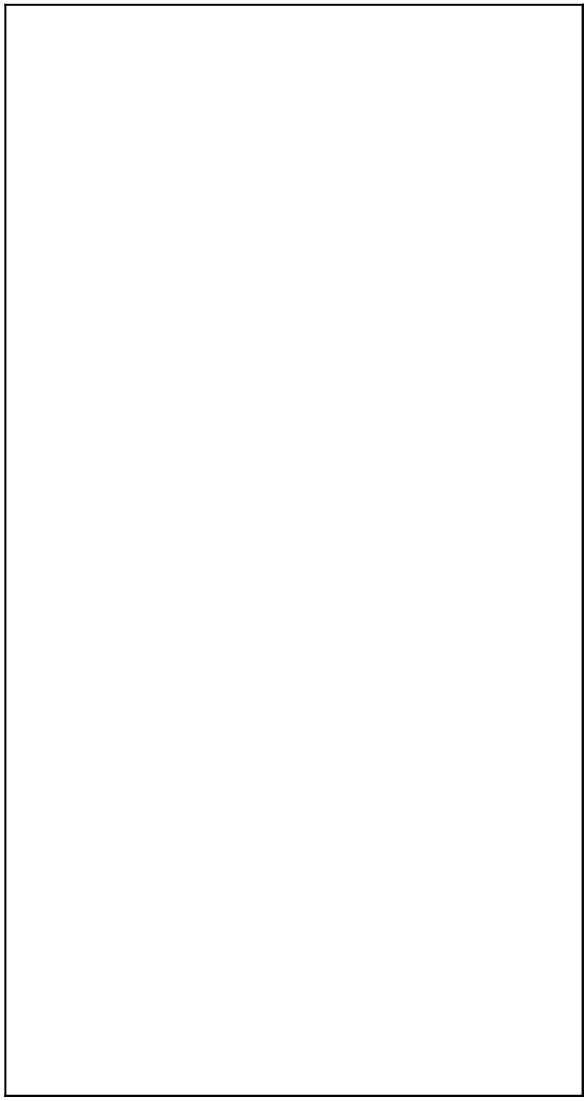
No benefit to the business.

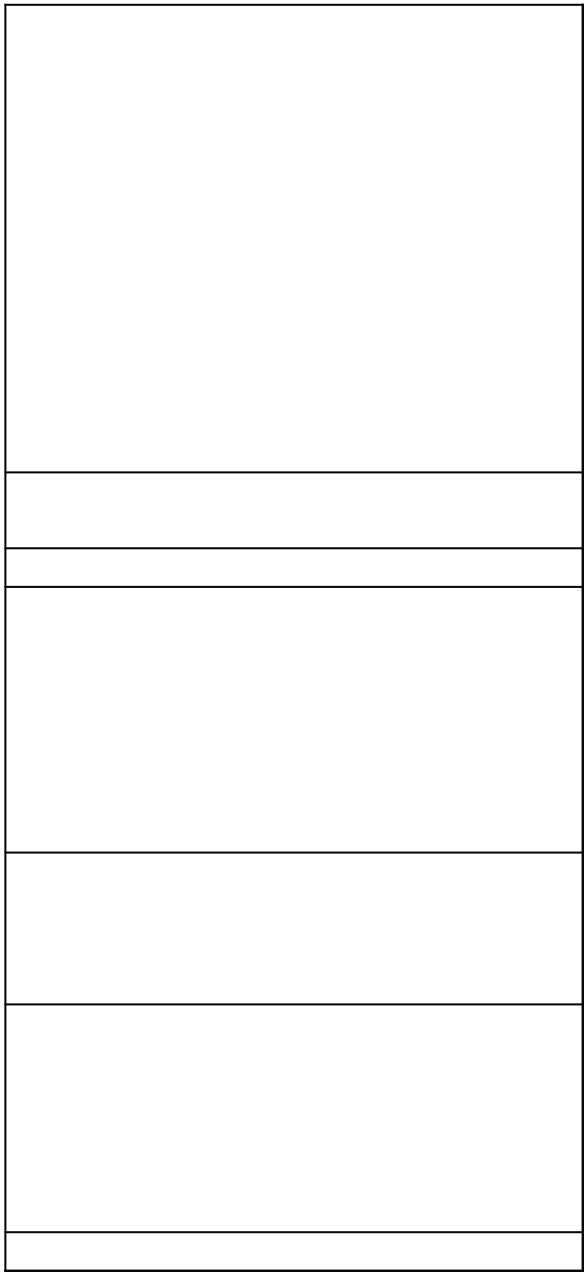


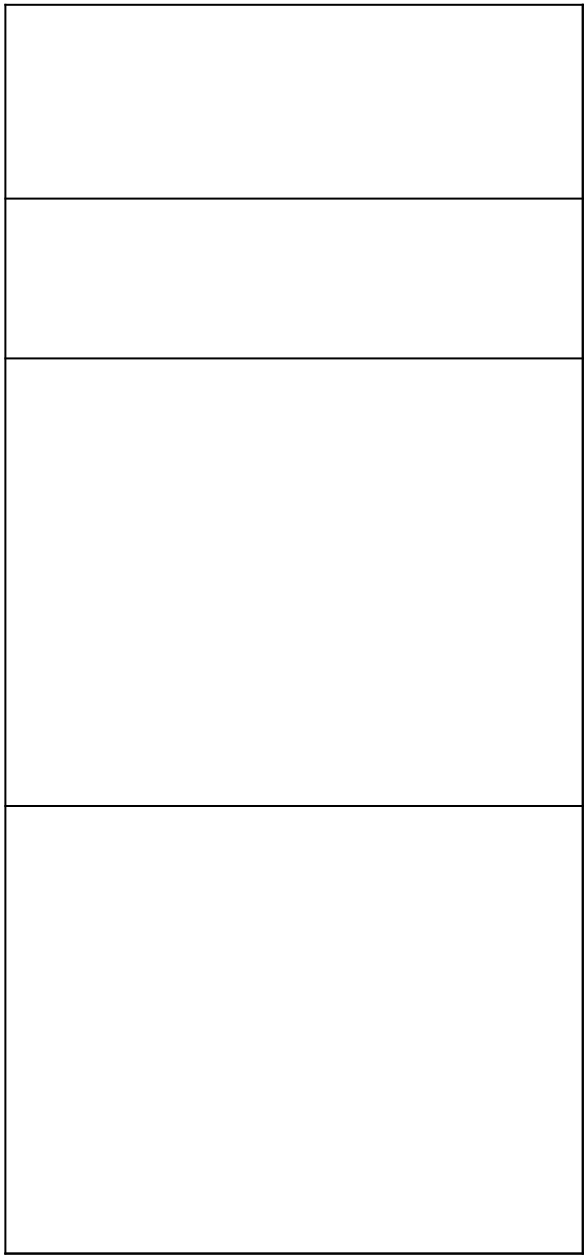


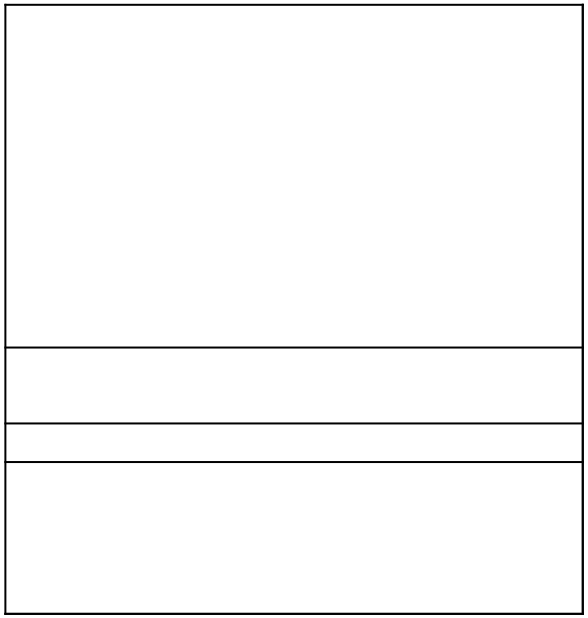


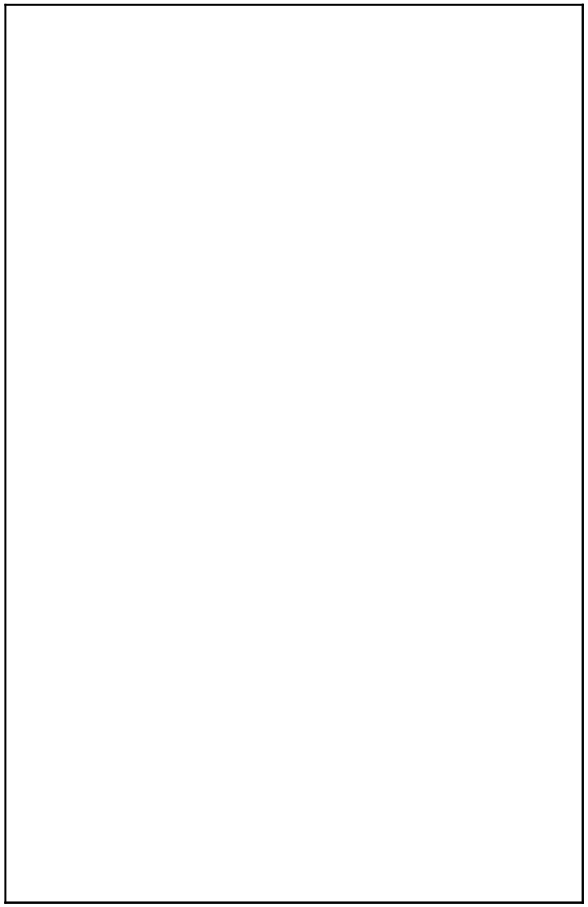


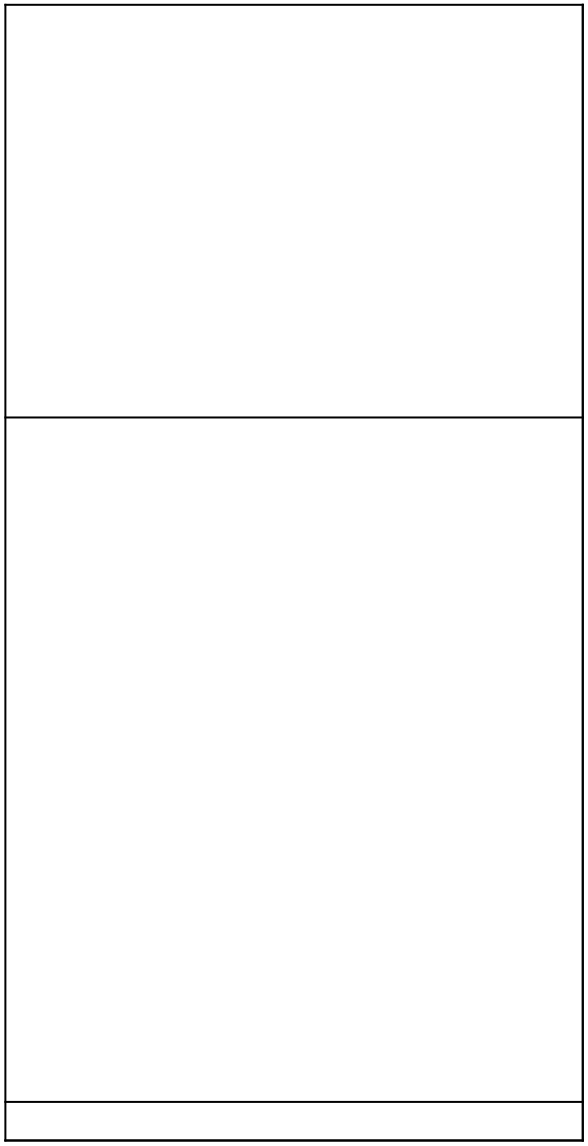


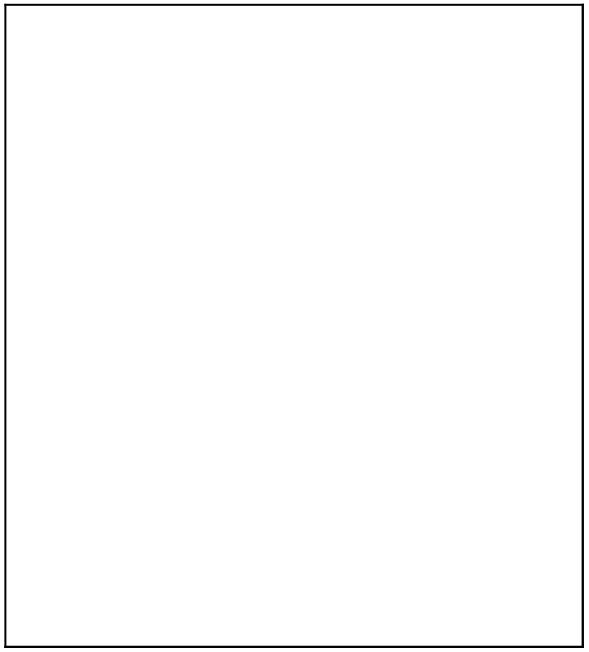












Other SEIA issues (e.g. are PFAS-containing medical devices a risk for the patients who use

IVD instruments are used in controlled conditions; the vast majorty being used by trained technicians in laboratories. Self test devices come with clear instructio
considered, including that from any chemical within the device. Any PFAS materials that could come in contact with the patient or clinical would be limited to skin
IVD devices would impact the avaibility of diagnostic tests on the EU/EEA market with the result that diagnostics of disease would be severely impacted, resulting
budget required to manage late diagnosis and increase deaths.

All devices containing PFAS lubricants have been assessed through a comprehensive battery of biocompatibility tests, in alignment with

No patient exposure is expected from normal use, as the PTFE membrane is not a device component which the patient would contact, to open or close the pro
Moreover, PTFE would impart little-to-transfer to skin during such incidental dermal exposures, since the contact time with the skin is also likely very mini
Companies report that the loss of chemicall inert filter membranes for minimal drug device interaction and high performace might re

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to incur more severe morbidity impacts. Open surgical procedures often include longer hospital stays, which typi

•Additional risk of infection (often corresponds with higher morbidity)

•Increased procedural time (often corresponds with increased length of exposure to anesthes

•Increased hospital stay length (often corresponds with higher healthcare practitioner burden, higher risk of infection or reintervention, increased emotional/menta

Some medical devices treat especially vulnerable patient populations, including babies and terminal cancer patients. Patient populations such as these often re
ensure fewer procedures, and generally improve quality of life.

Longterm experience with PFAS material uses in implantable devices

PFAS-containing (i.e., fluoropolymer-containing) medical devices have been implanted for 45+ years safely and effectively. Additionally, devices are MDD/MDR-ap
relevant biocompatilbiity tests (for human health matters). One of the benefits of PTFE is its biocompatibliity and durability, so that it can typically last the lifetim
following publication (Alzahrani N. The effect of hospitalization on patients' emotional and psychological well-being among adult patients: An integrative review. A
Epub 2021 Aug 12. PMID: 34544571.) shows that hospitalization demonstrably impacts patients' emotional health and increase

Sustainability:

With the global push for sustainability, the medical sector has been very active in exploring novel methodology in a highly regulated environment. R&D talent is exp
packaging, and even re-use of certain medical devices. These resources are also evaluating more sustainable manufacturing practices (such as electronification)
and more. It is likely that if this law were enacted, these same R&D resources would be displaced into seeking a fl

Broad Economic Impact:

Patients treated with minimally invasive procedures likely have a faster recovery time as opposed to invasive or open procedures. A faster recovery time can be
patient. A quicker return to the workforce can mean more time contributing to society, less insurance payments, increased feelings of productivity, maintenance of
company benefits), among other things.

Innovation:

If this law were passed, most or all of these resources would be displaced to support new non-PFAS products, which may actually be detrimental to the population,
dedicated to treating new disease states, seeking solutions for new patient populations, and solving unmet clinical needs would likely b

Environment:

Substances within the broad PFAS group represent inherently very different compounds with different chemical, physical and toxicological properties. Fluoropolym
environmental concerns. They are not bioavailable, do not have the potential to become widespread in the environment, and do not degrade in the environment.
groups, and not under the collective grouping of all PFAS.

Per Annex XV Table 1, annual polymeric PFAS used in the medical device industry makes up only 2.75% of the total (mid) estimated amount used across the m
devices, at 0.38% of all polymeric PFAS emitted to the environment across all major use secto

•Additional risk of infection (often corresponds with higher morbidity)
•Increased procedural time (often corresponds with increased length of exposure to anesthes
•Increased hospital stay length (often corresponds with higher healthcare practitioner burden, higher risk of infection or reintervention, increased emotional/menta

Unavailability of vascular interventions in case of unavailability of coated guidewires

A ban of guidewires, mainly with a PTFE coating, will be 18 month after EiF, according to the information from the applicants, if it is not covered by 6.j. This will in procedures, since no guidewires will be available on the European market. Another aspect is the availability of PFAS containing processing aids for the manufactu month after EiF.

A ban of Fluoropolymers will also have general impact on the availability of these polymers for medical devices. Therefore, the Fluoropolymer supply for medical d the applicants) will be affected, which will cause additional costs for substitution efforts and submissions (e.g. under EU MDR 2017/745). In a no-de

demonstrably impacts patients' emotional health and increases feelings of depression and anx

Compliance with biocompatibility

All devices have been assessed through a comprehensive battery of biocompatibility tests, in alignment with ISO 10993, s

Sustainability:

With the global push for sustainability, the medical sector has been very active in exploring novel methodology in a highly regulated environment. R&D talent is exp packaging, and even re-use of certain medical devices. These resources are also evaluating more sustainable manufacturing practices (such as electronification) and more. It is likely that if this law were enacted, these same R&D resources would be displaced into seeking a flu

Broad Economic Impact:

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Environment:

Substances within the broad PFAS group represent inherently very different compounds with different chemical, physical and toxicological properties. Fluoropolym environmental concerns. They are not bioavailable, do not have the potential to become widespread in the environment, and do not degrade in the environment. groups, and not under the collective grouping of all PFAS.

The consumer loses the option for PTFE mesh which could be less expensive and depending on the country/region may be the only option for adhesion-free abd
get trashed or sold for scrap; loss of cost effective adhesion-free hernia mesh; minimal impact on st

Tapes are used in various surgical procedures, such as those requiring tissue approximation, retraction, and as a temp

No (Risks from PFAS) - more details available in the case study on drug-device combination pro

ETFE coating have been used for more than 20 years in immediate packaging and integral drug-device combination of Human medecine like prefilled syringes with
and all biocompatibility testings done on the coated stoppers have shown that they are safe for use in pre
With no derogation the impact of European citizen health will be critical as it will result in Key Drugs shortages.We estimate that they are approximately 200+ mark
annually. Due to their sensitive nature many of these biologic drugs (in prefilled syringes) use a PFAS (ETFE) coated stopper. Examples of indications of these dr
and neutropenia.
We estimates that in represents between 240 millions and 480 millions of doses in prefilled syringes
No derogation will also have a high impact on innovation and future new drugs launches on the European Market. We estimate that there are approximately 100
expected to be launched in a prefilled syringe device with PFAS coated stoppers.

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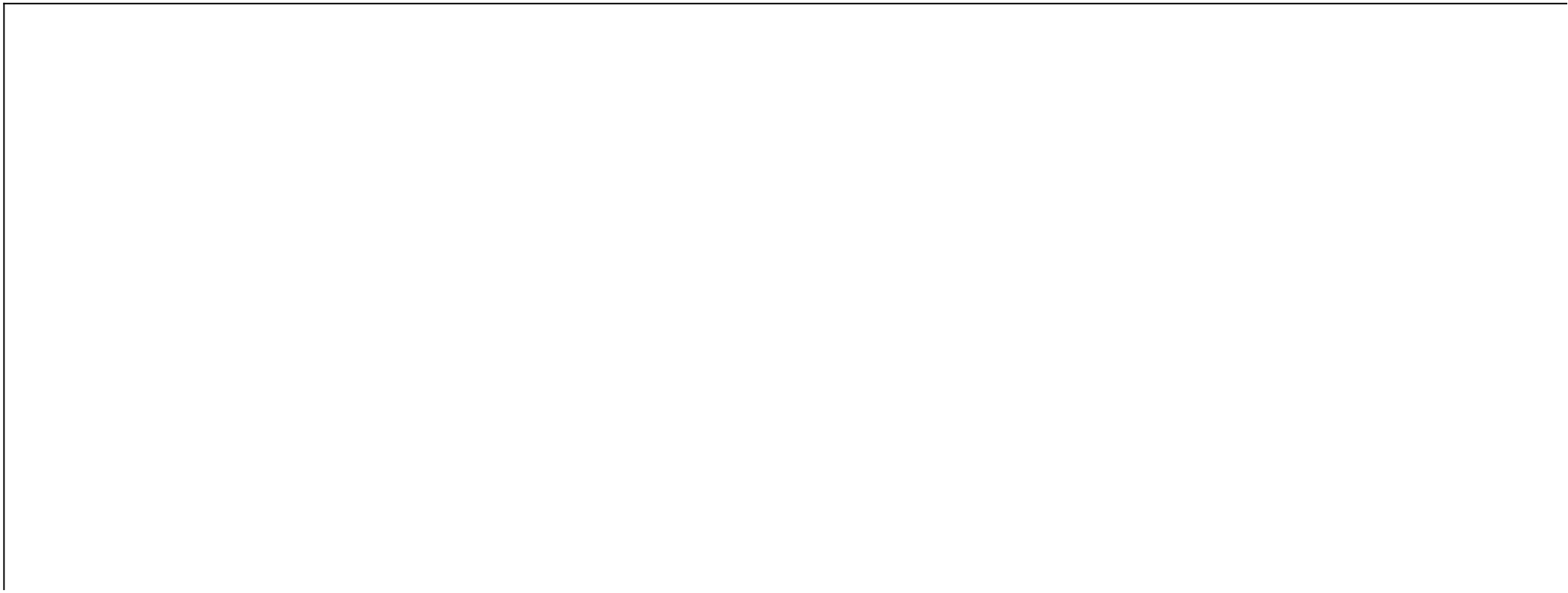
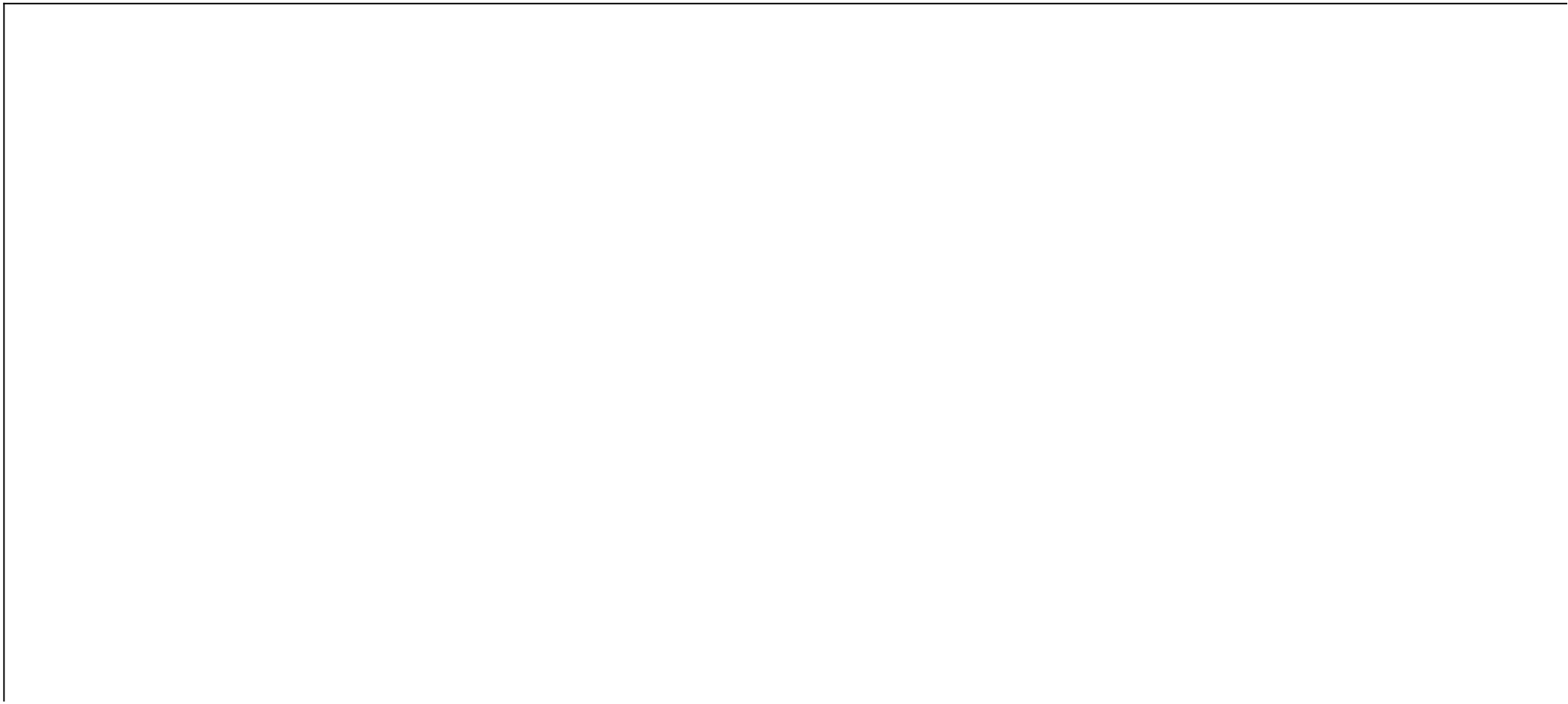
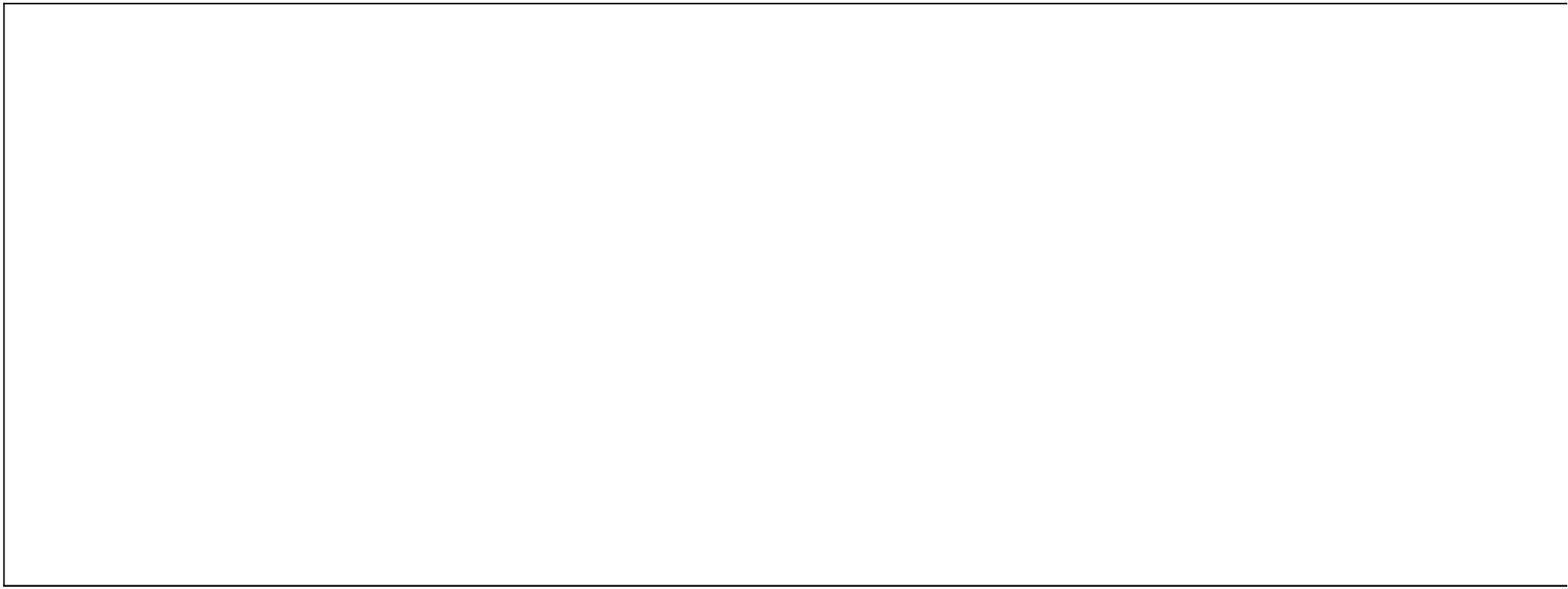
Removing these release liners from the market too soon would impact the availability of these specific medical adhesives from the market with focused adhesive
(e.g., but not limted to: Stomy medical adhesives or dementia/ parkinson's transdermal treatement). In particular, impact on the availability of transdermal drug deli
avoid over-dosing or oral treatment (e.g., but not limited to: treatement for patients who can not swallo

For other uses, CONFIDENTIAL DATA IS AVAILABLE.







Medical technologies and their packaging have been assessed through a comprehensive battery of biocompatibility tests, in alignment with ISO 10993, supporting
and do not directly contact the patient.

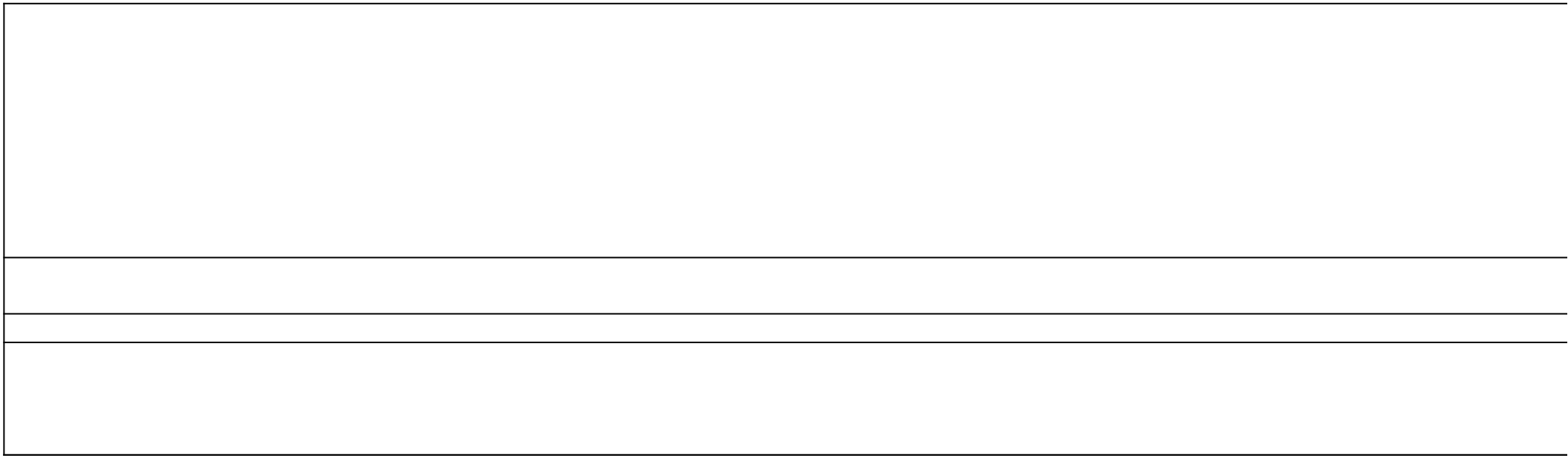
In cases where the PFAS material is internal to the device, there is no patient contacting biocompatibility risk. For cases where there is non-invasive patient cont
10993, supporting a lack of patient risk.

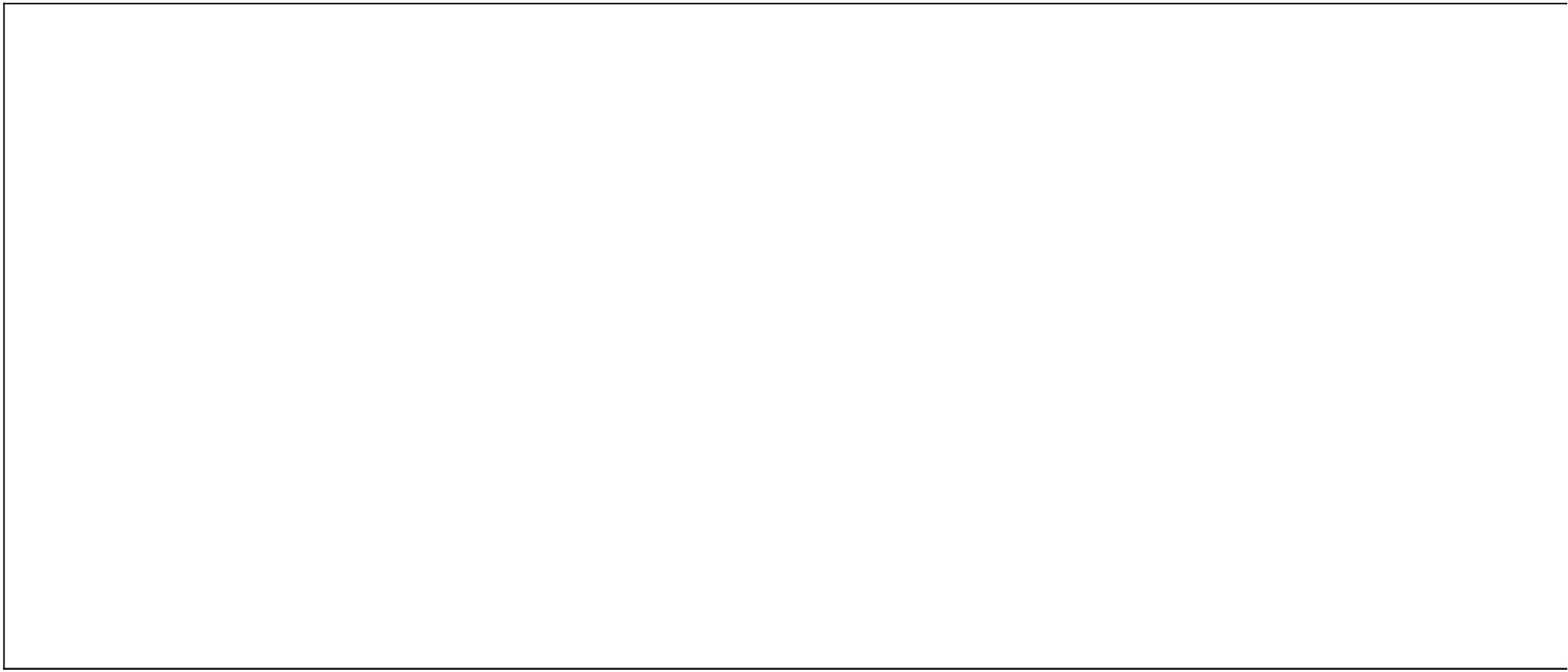
For blood glucose meters and test strips, in case of a no-derogation scenario, if we cannot ensure future supply of products due to lack of PFAS alternative
We expect our competitors to face similar challenges, therefore their products would not be an alternative for c
The scenario of loss of market shares/sales is less likely to happen, however, a real effect will be that diabetes management and therapy in ge
Patient safety is the first and foremost responsibility of a medical device manufacturer. Therefore, as for basically all medical devices, the design change processe
if a material with comparable properties is found, the process until it can be registered on the different markets can take several years. This does not include the ti
consuming.
In addition, this would influence the cost for patients and customers, as well as medical insurances tre
Since medical devices make up for a rather small part of material usage worldwide, a restriction of PFAS containing substances within the EU may cause suppl
medical devices within the EU. Additionally, a shortage of possibly alternative materials may arise due to a sudden high dem
In the end, this affects the patients and customers, because the provision with the respective devices can

All currently marketed devices have been assessed through a comprehensive battery of biocompatibility tests, in alignment with ISO 10

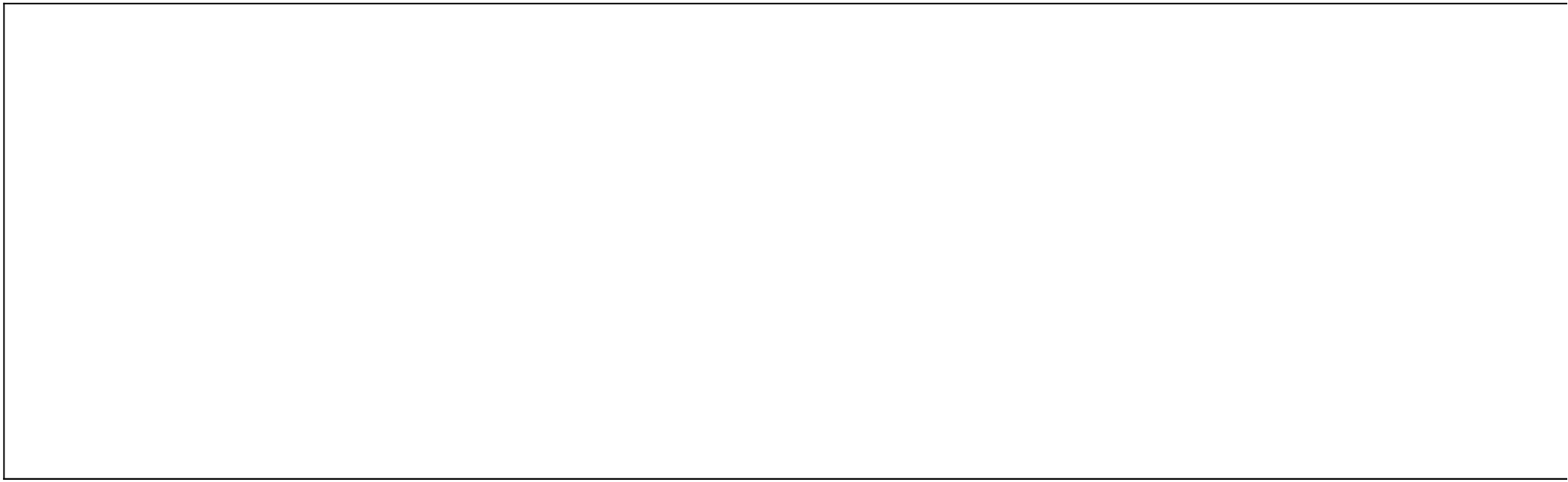
According to a review of the Intelligent Research in Sight Registry (IRIS) database, retinal detachment occurs in approximately 18 out of every 100,000 people. Re can result in loss of sight. Since retinal detachment is strongly correlated to increasing age, it is likely to increase in the general Treatment via pneumatic retinopexy is successful for 9 out of 10 people (Saraf et al., 2022) however is not an option in the ma Vitreoretinal surgery is required in the majority of retinal detachment cases and again has a high rate If ocular gases are no longer available, silicone oil would be the available tamponade alternative, requiring additional surgeries to remove the tamponade, increa outcomes.
Many medical devices, for example, those used to treat orthopedic trauma, and those used in craniomaxillofacial reconstructive surgery and veterinary / animal sur and O-rings (e.g., PTFE), which do not appear to be derogated otherwise. As components of highly regulated medical devices, even the replacement of a seal or material, may affect the fit and function of the device, and hence would trigger the same regulatory timeframes required of other medical device redesign efforts, fr to reregistration in global markets, followed notified body conformity assessment—in total this process may take up to 12 years, in particular if there

Marking with the ink on medical devices and device part of a drug-device combnation products for identification, scale, measurement, size, and other functional att in medication errors and eventually high risk outcomes. Without marking, the medical practitioner would not know how much drugs they are administrating to the patient or would not be able t Patients' health will be directly impacted if the there are no printing available on the medical devices which is critical for th
O-rings: many medical devices, for example, those used to treat orthopedic trauma, and those used in craniomaxillofacial reconstructive surgery and veterinary / based seals and O-rings (e.g., PTFE), which do not appear to be derogated otherwise. As components of highly regulated medical devices, even the replacement non-PFAS material, may affect the fit and function of the device, and hence would trigger the same regulatory timeframes required of other medical device redes efficacy testing, to reregistration in global markets, followed notified body conformity assessment—in total this process may take up to 12 years, in particula





Entire product lines and therapies will no longer be offered for sale in a no-derogation scenari
Customers will demand a product that serves the needs of the patient, but without a full derogation there will be no product (containing fluoropolymers) for sale, as
This extends to the patients of hospitals, who will be left with fewer or no solutions to health issues that they are experiencing, particularly in areas with high mark
with. In addition, if fluoropolymer manufacturers exit the market, suitable products won't be available
The only current technology replacements for minimally invasive products would be open-heart surgery with much m



Transitional period/deferred entry into force

13,5 years+

Any removal of PFAS from multiple components of a complex IVD device would take in excess of the proposed 13.5 yrs. Assuming suitable alternatives were kn
provides, long validation and verification processes and well as regulatory approvals would be required under sectorial legislation before complete substitution was
will lead to the unavailability of these devices on the EU market compromising patient health.

13,5 years

As no alternative material has so far been identified and considering the implementation time after an alternative is identified, we are requesting the maximum trans
force.

13,5 years

Request for a review of this derrogation prior to it's elimination in 13.5 years to determine if this derrogation is still needed.

13,5+ years

12 years

PTFE membranes are used in the venting of Class II medical device liquids; the membrane is in direct contact with the disinfectant solution, which has direct patie
years to substitute with a non-PFAS material (no non-PFAS material replacement has been readily identified after two years of research), since this first requires
qualified, then a production process must be developed and qualified, then pre-clinical testing must be completed, followed by clinical phase submissions and ap
then clinical trial follow-ups, then clinical trial reporting, then process validations must be completed, followed by commercial regulatory submissions and approv
years, even for the simple replacement of a PTFE membrane in a medical device, but importantly, if a non-PFAS alternative materials doesn't even exist, it could t
time required to invent a novel material, as this would occur upstream from the medical device manufacturers).

12 years are needed at the minimum for finding and validating alternative to PTFE coated filter membranes, if the alternative is meeting the func

13.5 - 30 years
Potential language for the derogation:

1. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers which are used in implantable medical devices and Clas
devices within the scope of Regulation (EU) 2017/745.

OR

2. By way of derogation, paragraphs 1 and 2 shall not apply to implantable medical devices and Class IIb and Class III invasive medical devices within the scop
derogation shall be reviewed under Annex XV after a period of 20 years.

20+ years

20+ years will be required to find alternatives or redesign the product. Tubes and Catheters needs to include all of the possible tubes and catheters used in med
heat shrink, wire insulations, cables, sheaths, etc. Currently, there is no alternative to PTFE, FEP and PVDF.


20 years

12+ years

Wound care includes simple items like gauze and bandaids, but does not necessarily capture specialized devices like percutaneous vessel closure devices that a many surgical procedures to be executed as out-patient procedures. The Derogation category needs to be separated for these types of specialized devices that specialized and designed. These designs require a longer derogation period, because alternate materials are not readily available and/or may not exist. In the eve are unavailable then these types of devices that provide significant benefit to the healthcare system may cease to exist.

Redesign in medical devices requires up to 12 years, when the change impacts form, fit or function of the device; the material composition changes needed form/fit/function of the device. In addition, such a change first requires a non-PFAS material to be identified and qualified (no ready replacement is known to exist developed and qualified, then pre-clinical testing must be completed, followed by clinical phase submissions and approvals, then clinical trial enrollment, then clin reporting, then process validations must be completed, followed by commercial regulatory submissions and approvals--in total, this requires up to 12 years, but in material doesn't even exist, it could take even longer (difficult to predict the time required to invent a novel material, as this would occur upstream from the r

20+ years

Longer derogation time than 13.5 years is needed, as no alternative currently available. PTFE used in Guidewire to guide catheters to the intended area of the b
guidewires must offer excellent biocompatibility, moderate tensile strength, good corrosion resistance, as well as moderate fatigue and relaxation resistance. The
that offer the lubricity to easily manoeuvre around the body. Without PTFE, this is not possible.

The 18 months transition period is not sufficient.

Even when alternatives are available, timelines above 10 years are needed to validate an alternative (see column G for details). For sensitive medecines like biolog
available timelines for subtitution are even longer (above 12 years-see column G for details).

This is inherent to the industry sector which is a highly regulated environment. Requirements of Both device regulation (EU MDR 2017/745) and Human medicine
when making a change to an integral drug device combination product leading to long timelines (much longer than the 18 months of tr

Other release liners such as PVC, Polyethylene have been tested as alternative to Fluoropolymers coated liners without success. Currently, there are no straig
requested properties.

Finding a replacement release liner will be complex and will take time in view of unfruitful past trials. The identification of a liner replacement or the potential devel
validation, extractions, biocompatibility testing, and regulatory approval of a material substitution could take more than 12 years taking into account the lack of dir
benefit from the currently 13,5 year proposed derogation.

Patient safety is the first and foremost responsibility of a medical device manufacturer. Therefore, as for basically all medical devices, the design change processes
are extensive and lengthy. Even if a material with comparable properties is found, the process until it can be registered on the different markets can take several y
the registration process with the countries itself, which is also time consuming.
In addition, this would influence the cost for patients and customers, as well as medical insurances tremendously.

12+ years

Redesign in medical devices requires at least 12 years, when the change impacts form, fit or function of the device; the material composition changes neede
form/fit/function of the device. In addition, such a change first requires a non-PFAS material to be identified and qualified; then a production process must be deve
testing must be completed, followed by clinical phase submissions and approvals, then clinical trial enrollment, then clinical trial follow-ups, then clinical trial report
completed, followed by commercial regulatory submissions and approvals--in total, this requires at least 12 years, but importantly, if a non-PFAS alternative mate
even longer (difficult to predict the time required to invent a novel material, as this would occur upstream from the medical device manu

13.5+ years

Packaging is considered part of the IVD under sectorial legislation and any changes to packaging may require approval of the notified bodies. As such the 13.5 yr
with sectorial legislation.

12+ years

Redesign in medical devices requires at least 12 years, when the change impacts form, fit or function of the device; the material composition changes neede
form/fit/function of the device. In addition, such a change first requires a non-PFAS material to be identified and qualified; then a production process must be deve
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even longer (difficult to predict the time required to invent a novel material, as this would occur upstream from the medical device manu

13,5 years

13,5 + years derogation is at least needed to identify, redesign, qualify and validate the alternative, and obtain the required regulatory approval. Full derogation rec

MD/ IVDs.

13,5 years

As no alternative material has so far been identified and considering the implementation time after an alternative is identified, we are requesting the maximum trans
force.

13,5 years As no alternative material has so far been identified, and considering the implementation time after an alternative is identified, we are requesting the maximum tra into force.
Derogation for industrial use of Fluorosolvents in the manufacture of IVD use would be required to align with the IVD derogation
13.5 years A derogation of 13.5 years after EIF is needed to further evaluate alternatives. Due to their close contact with critical materials and drugs, regulated design contro changes.

10 years Discovery of an alternative is difficult to predict but anticipated as taking at least 10 years or more as they would require clinical trials to support
12 years Tubings: Redesign in medical devices requires at least 12 years, when the change impacts form, fit or function of the device; even a change in the material compo portion of the phacoemulsification device, to its drip-port component; the luer also comes into contact with invasive fluids, which are inserted into the body during through the connected tubing) may indeed impact the form/fit/function. In addition, such a change first requires a non-PFAS material to be identified and qualified developed and qualified, then pre-clinical testing must be completed, followed by clinical phase submissions and approvals, then clinical trial enrollment, then clin reporting, then process validations must be completed, followed by commercial regulatory submissions and approvals--in total, this requires at least 12 years, even a medical device, but importantly, if a non-PFAS alternative materials doesn't even exist, it could take even longer (difficult to predict the time required to invent a upstream from the medical device manufacturers)
Patient safety is the first and foremost responsibility of a medical device manufacturer. Therefore, as for basically all medical devices, the design change processes are extensive and lengthy. Even if a material with comparable properties is found, the process until it can be registered on the different markets can take several y the registration process with the countries itself, which is also time consuming. In addition, this would influence the cost for patients and customers, as well as medical insurances tremendously.

12 years At least 12 years are needed to find a non-PFAS substitute, since none are clearly identifiable, and these devices require at least 12 years are needed to bring to which may impact form, fit or function, such as a material such w/ a non-PFAS substance)
The 18 months transition period is not sufficient to phaseout PFAS. Even when an alternative is available,more time is needed to validate change, plus additio implement change (likely moderate to high impact to drug applications). A derogation of 13,5 years after EIF is needed to evaluate alternatives, validate and qualify the most promising alternative.
For many medical devices (e.g. the surgical laser equipment used to perform LASIK surgery on the eye, or robotics being used for endosurgical procedures), we r in a 20 year period, but during that 20 year period, certain components inevitably break-down (e.g. monitors, power cords, keyboards, etc.), and as a result, w components, and when we sell a stand-alone monitor or keyboard (for example), this stand-alone monitor or keyboard is not regulated as a medical device, henc proposed medical device derogations herein, and instead we need an additional derogation for medical device spare or replacement parts a
For many medical devices (e.g. the surgical laser equipment used to perform LASIK surgery on the eye, or robotics being used for endosurgical procedures), we r in a 20 year period, but during that 20 year period, certain components inevitably break-down (e.g. monitors, power cords, keyboards, etc.), and as a result, w components, and when we sell a stand-alone monitor or keyboard (for example), this stand-alone monitor or keyboard is not regulated as a medical device, henc proposed medical device derogations herein, and instead we need an additional derogation for medical device spare or replacement parts a

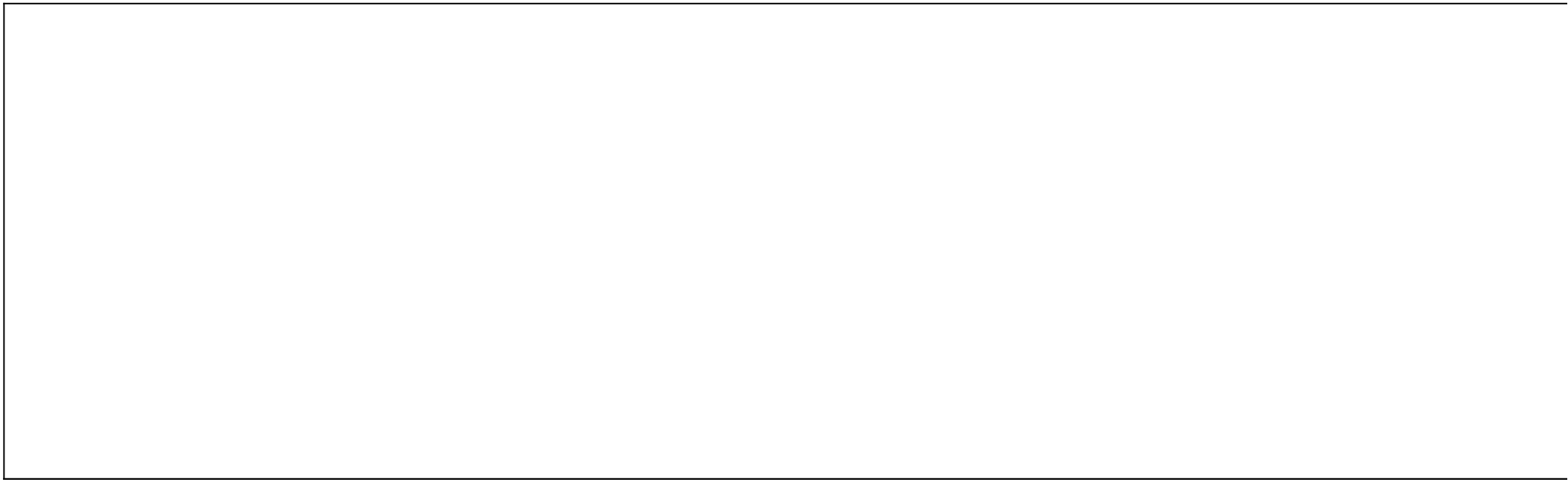
Since medical devices make up for a rather small part of material usage worldwide, a restriction of PFAS containing substances within the EU may cause supplie
hence disrupt the distribution of medical devices within the EU. Additionally, a shortage of possibly alternative materials may arise due to a sudden high dem
In the end, this affects the patients and customers, because the provision with the respective devices cannot be ensured.

12 years Even the replacement of a seal or O-ring made of PFAS, with another seal or O-ring made of a non-PFAS material, may affect the fit and function of the device regulatory timeframes required of other medical device redesign efforts, from new biocompatibility testing, to new clinical trials and efficacy testing, to reregistratio body conformity assessment—in total this process may take at least 12 years, in particular if there is no ready alternative available and it m
13,5 years The 18 months transition period is not sufficient to phaseout PFAS. Even when an alternative is available,more time is needed to validate change, plus additio implement change (likely moderate to high impact to drug applications). A derogation of 13,5 years after EIF is needed to evaluate alternatives, validate and qualify the most promising alternative.

13,5 years

Considering the implementation time after an alternative is identified, we are requesting the transition time of 13,5 years after entry in

13.5 years
12 years Since medical devices make up for a rather small part of material usage worldwide, a restriction of PFAS containing substances within the EU may cause supplie hence disrupt the distribution of medical devices within the EU. Additionally, a shortage of possibly alternative materials may arise due to a sudden high dem In the end, this affects the patients and customers, because the provision with the respective devices cannot be ensured. b. PTFE used for suture: Transition from PTFE to another equivalent monofilament technology will require at a minimum a 12 year derogation for a safe transition There is currently no clinical data available for other equivalent polymers which is needed for clearance under EU sectorial legislations (e.g



1. Implantables

Interventional cardiac occluders and endoprostheses, surgical vascular grafts, cardiovascular patches, surgical sutures, i
effectively. Fluoropolymers are biocompatible, bioinert, stable when implanted, durable, non-toxic, chemically and heat re
history of fluoropolymers. Not-yet-discovered alternatives may not be able to serve as diverse a patient population as wha
[and invasive] medical devices is a drastically more complex and resource-intensive undertaking than in most other applic
would take ~20 years for a single device. For patient contacting and implantable devices, special requirements for carci
includes a risk-benefit analysis. Currently, over 1,200 CMR/ED substances need to be addressed under Section 10.4 of the
manufacturing.

2. Complex equipment – e.g. equipment for organ replacement (active medical devices)

One example of concerned complex equipment are devices which are used to replace essential body functions in case
hundred different components, consisting of several different fluoropolymers. Uses include e.g., parts of valves that must be
of concerned parts. Besides the above-described active medical devices, PFAS are also relevant for manufacturing and p
technical and regulatory conditions. In the majority of components, a material change would also impact the tools used in
considered. Concerned devices are investment goods, intended to be used in clinics and hospitals for several years. Thu
change of the product design and related tools must follow strict rules and processes to comply with applicable quality, safe
at all, would take more than six years. Needed internal and external resources for technical qualification, bio-compatibility
analysis of potential alternative materials, design changes, change of tools etc. could only start after identification of a com
case of electrical components, manufactured and supplied in a multi-tier supply chain. Due to the broad scope and low th
specified material of a supplied mono-material component. Experience with RoHS showed that generation of reliable and
and re-design of components by concerned suppliers is highly questionable.

3. Complex equipment – e.g. IVD analytical equipment

Another example of concerned complex devices are IVD analytical equipment. Polymeric PFAS materials, including PT
analyzers. Specific examples include tubing and O-rings. One particular example is for dispensing accurate volumes of l
inaccurate volume would be dispensed for the reaction, leading to inaccuracies in diagnostic test results. Another exam
components, leading to increased downtime which ultimately result in delayed patient results. For both of these presented
13.5 year timeline will be much too short for an adequate replacement material to be identified and to be proceed through th

4. IVD regeants

PFAS substances are used in IVD devices such as IVD testing kits for hemostasis products (at an extremely low concer essential to the functioning of the instrument. The PFAS substance is needed to maintain the temperature of the reactio reagents and systems fluids are required under specific regulations to adhere to design change procedures that can take country where sold (can be up to 42 months). This is for one substance only. When considering that a group of PFAS cou time in case of materials with contact to blood or similar criticality is approximatively 3 years and can further exceed this similar criticality, the minimum approval time is approximatively 3 years and can further exceed this range. Additional use o in high-performance liquid chromatography applications and as an ingredient. Additionally, polymeric PFAS materials are Unfortunately, no derogation has been given for these use cases. The reason for using these PFAS materials is primarily using PFAS materials could have a significant impact on the supply of IVD reagents upon the effective date of the restrictio

5. Prefilled syringe stopper - A device constituent of an integral drug-device combination

Glass prefilled syringes are today widely used within the European market for Health treatments. We estimate that appr syringes) use a PFAS (ETFE) coated stopper. Examples of indications of these drugs include but are not limited to mul minimizing the risk of interaction between the rubber stopper and the Drug during its shelf-life. A well know example for incidence of pure red cell aplasia. For sensitive Drugs substitution of PFAS coated stopper by PFAS free stoppers is not PFAS coated stoppers with regards to extractable impurities. With existing PFAS free stoppers, the risk of adverse health impact of European citizen health will be critical as it will result in Key Drugs shortages (200+ Biologics sold on the EU ma there are approximately 100+ biologic drugs in clinical trials across the European Union that are expected to be launched regulated products: requirements of both, Medical device regulation (EU2017/745) and Human medicine directive (2001/83 We estimate that 240 to 480 millions Units of PFAS coated stoppers are used on the EU market for marketed drugs and cli Transformation of this supply capacity will require significant time and investments as all manufacturing equipments will hav

Redesign efforts have been initiated but we estimate that more than 12 years are needed for substitution:

- Redesign-timeline unknown but estimated at least to 4 years
- Stabilities Studies by pharmaceutical companies[4]- 3 to 5 years
- Manufacturing qualification- 9 months
- Regulatory approval from the device side[5] and the drug side[6]-2 years
- Industrial ramp up-6 months

[1] From IQVIA database (https://www.iqvia.com/) -detailed report can be shared upon request

[2] "The increased incidence of pure red cell aplasia with an Eprex formulation in uncoated rubber stopper syringes"-Kidney

[3] Estimation was made from Global data 2023 (https://www.globaldata.com/) and IQVIA (https://www.iqvia.com/) database

[4] ICH Q12 Technical and regulatory considerations for pharmaceutical product lifecycle management - Scientific guideline

[5] Notified body Opinion on Annex I of (EU) 2017/745 shall be obtained on the device side of the integral Drug device com

[6] Variation to the existing marketing authorization approval

6. Blood Glucose Meters (IVD) for diabetes treatments

Diabetes is one of the big health topics with an incidence of one in elevent adults in the EU. Blood glucose measurement meters (BGMs) are designed as affordable appliances. PFAS are widely used in electrical appliances, also in printed circ PFAS was never really considered as concern, the use of PFAS in PCBs and others electrical components is expected to (BGMs) are designed as affordable appliances. Alternative materials, since they are quite rare, can be very cost intensive will make the distribution of affordable medical devices for all patients even harder. Patient safety is the first and foremost r Therefore, as for basically all medical devices, the design change processes required in order to change materials are ext does not include the time of the registration process with the countries itself, which is also time consuming. This again wou worldwide, a restriction of PFAS containing substances within the EU may cause suppliers to terminate their production a from several manufacturers. In the end, this affects the patients and customers, because the provision with the respective

7. Immunnoassay cartridges

The current packaging for the immunoassay cartridges of a clear, formed container is using Techniplex Aclar (PCTFE). A
allows for the product to be identified easily through the clear, formed material. There are features of the cartridge that ma
rates are thicker which may cause problems with assembly. Characteristics such as material tensile strength, clarity, water
year of shelf life of the product. The devices are quite sensitive to moisture and the long-term impact will need to be validate

8. Guidewire for coronary and peripheral interventional application

Guidewires are an integral part of vascular intervention. They are utilized to access target vessels, cross lesions, and deliv
design requirements for guidewire dependent on the lesion type and clinical presentations, one requirement is universal for
the friction. However, at the proximal end of the guidewire, a hydrophic dry/wet lubricious coating is needed, because the
Alternatives to the use of PTFE as the coating on the proximal end of the guidewire have been evaluated multiple times ov
The performance evaluation included direct friction measurements as well as in-vitro bench testing where the alternative m
of vessel through an access point a distance from the diseased segment. The guidewire is the fundamental tool used by int
of guidewire deliverability with minimum resistance in tortuous anatomy and in the delivery of therapeutic devices. Any incre
be treated today. Therefore, a redesign of the guidewire coating will not meet the customer need without a dry lubricious co

9. Vessel closure devices for large bore procedures

Vessel Closure devices are an integral part of large bore arterial procedures, because they allow for the safe, and non-surg
and are undergoing percutaneous procedures in many cases specifically because of their overall health (e.g. a surgical c
vessel closure devices allows the avoidance of surgical closure of their access sites, significantly increasing their chan
process/ambulation. These devices and their percutaneous delivery rely upon low coefficients of friction to function correct
perform their functions. Alternatives could require lubricating the devices prior to use, or the addition of some other hydrop
tools for interventionalists. Redesign of these tools is possible, but still must meet the basic requirements of operating in a
needed to be avoided in the first place.

10. Implantable tissue-based heart valve

Implantable tissue-based heart valve is indicated for patients requiring replacement of a diseased, damaged, or malfuncti
holder attachment. V2 added a new valve configuration, which had higher constriction forces in the holder. As a result, th
added benefit of lowered patient trauma in the form of lubricity, as the retention/attachment sutures on the holders are remo

11. Surgical energy device

Biocompatibility, chemical resistance (acid and alkali resistance), heat resistance, mechanical properties, flame resistance, energy treatment devices, and it is a material that can achieve the above properties at the same time. In particular, PTFE, v companies as well. There are no alternative materials, so it is impossible to start redesigning our products with substitution. registration under EU MDR. (Testing of alternative of materials/components: Reliability testing; redesign of product for an al requirements apply)).

12. Peripheral stent graft (endoprosthesis)

A high-level material transition roadmap has been created to outline what would be necessary to replace fluoropolymer film Assumptions baked into this model include that the facilities currently have the capability to manufacture prototypes usir current device manufacturing process. The estimated model is a “best case” scenario and does not yet include the prob changes may be necessary to accommodate changes in film properties. Note that these generous assumptions likely und commercialization (10 years - overlap with manufacturing) would take a total of 16 years at a minimum (best case). A deta which have over 45 years of successful history in implamantable medical devices, we are not aware of this particular polym

13. Contact lens disinfectant

Product contains a PTFE membrane used to vent oxygen gas formed during disinfection of contact lenses; the membrane water from migrating through it, thus preventing the inner hydrogen peroxide solution from leaking or spilling. The PTFE determined to be incompatible for our application by the membrane supplier, since neither will allow proper bonding of the r Unfortunately, neither the two potential alternatives have proven to be viable PTFE, following completion of various critic sealed to, etc.); other porous, hydrophobic, chemically inert materials will likely need to be identified and tested over the cor

14. Printing inks for markings on medical devices and on the device part of an integral drug-device combination

Fluorinated waxes are used, by itself or in combination with other waxes as an anti-rub and slip additive in printing inks. The Printing inks are used to create markings for identification, scale, measurement, size, and other functional attributes on med of marking on the device. In case of medical devices such as syringes, inaccurate markings or lack of such markings will re This will adversely impact the health of the patient due inaccurate amounts of drug administered. The consequences could patient.
There are no currently available known alternatives, which are ready for evaluation through R&D. Once an alternative woul biocompatibility testing and may also require clinical trials, dependent on the application and location of the printing inks. A significant process development is anticipated after the formulation is finalized and passes all the biocompatibility testing in alternatives.

15. Robotic arm

PFAS (FEP, ETFE, PFA) are used in main cable assembly of robotic arms of an angiography system. Combination of more cables, power supply cables, control cables, signal cables etc. Most of the individual cables are multifilament cables. Parts PFAS are used for insulation action as the thickness of insulation is a key factor of cable assembly bending capability. PFA downgrade of system performance. A thicker cable assembly will no longer fit into the robot construction.
They are also used for their sliding and non-sticking properties, as low friction sliding of the individual cables among each o (bend radius, bend velocity) will decrease and wear will increase. This will lead to a downgrade of system performance, red emergency surgery. and a system failure can be fatal.
Finally, they are used for their flame retardant properties, because fire safety requirements are extremely high for medical s retardant properties in one substance. There is no comparable material available to fulfil all these requirements in parallel.
100% substitution will be impossible due to the wide range of outstanding properties of PFAS. Substitution with downgrade
Time for development is not sufficient, no matter how much resources are provided for this task: development of cable asse would have to be taken from the market, as only 50% of PFAS in the cable can possibly be replaced prior mid-2030 (in the less challenging. Some construction redesigns have to be done.
At their end-of-life, the robotic arm is taken back, resold, or upgraded.

16. Magnetic resonance imaging systems (MRI systems)

PTFE is used in cables and sleeving in low temperatures due fir its insolation action, as PTFE has a very low dielectric cons where other materials may be prone to electrical breakdown. In addition, PTFE has a very high dielectric strength, which is applications, which are common in many low-temperature environments.
PTFE has a very low thermal conductivity which means that it does not transfer heat very well. This is important in low-temp temperature.
PTFE is highly resistant to chemicals, including most solvents and acids. This makes it an excellent choice for use during m
PTFE maintains flexibility for cable bending and positioning without cracking during temperature transition from room tempe irreparable damage to the magnet system.
At the moment, there is no technical alternatives known with similar properties as PTFE against extreme conditions (low ter safety & reliability tests within 2 years. Therefore, the product would have to be taken from the market, and thus, it would re development in pharmaceutical industries).
At their end-of-life, MRI scanners are taken back, refurbished, resold, or they are upgraded, repaired or reused.

17. Blood Gas Systems

PFAS (PTFE) are used in main cable assembly of varying lengths and conductor count in Blood Gas systems, in special de
Structural Polystyrene Foam is used in instrument housings.
PTFE insulators can be very thin and minimally impact thermal measurements while still providing the necessary electrical i
PTFE is used to satisfy UL 94 V-0 requirements to self-extinguish and open flame is essential to satisfy fire safety standard
It is used in mold-release applications to allow molded part to be removed from the mold with fewer ejection pins. This is re
Substitution materials do not meet all of the requirements of the current design. Any alternative will downgrade system relia
vendors, convert old vendors to new suppliers, qualify untested materials, complete engineering verification and clinical vali
Many products are made with vendor proprietary formulations that are found to include PFAS. Plastic molded parts that do components previously believed to be PFAS-free.
There is no confidence that any of the above products can be certified 100% PFAS free within 2 years.
The main challenges are identifying all PFAS in the supply chain; coordinating with many vendors and design changes simu performance with PFAS-free materials.
When it comes to the end-of-life, instruments can be used for many thousands, or even millions of tests over their service li parts). Electronics and PCBAs can be recycled, but uncertain of fate of circuit board.
Multi-use cartridges and Single-use cards are biohazardous waste, which is typically incinerated depending on user laborat
PFAS is in some wiring components, printed circuit board assemblies, moving mechanical assemblies (within hinges, sides
Oxygen sensor is deep within the measurement cartridge in a location the user cannot access. Service personnel do not ac

18. In-vitro diagnostics devices (IVDs): Laboratory Systems

IVDs are used to detect patient illnesses, infectious diseases and to determine the effectiveness of medical treatment.
The potential for the presence of PFAS in tubing purchased from suppliers and/or use of PFAS in suppliers' tubing producti
PFAS are used for insulation and chemical resistance purposes, as chemical resistance in IVD tubing is of the utmost impo
future, the impact of a change is highly significant.
If tubing or electronic wire components containing PFAS must be changed, potentially > 100 IVD laboratory diagnostics dev

Tubing: The use of tubing in IVDs is extensive, as it is used to transport patient samples through an IVD analyser and to co
sensor detects a signal. The IVD devices' software is custom-programmed to report the clinical result of the IVD test, based
When tubing contacts patient samples and reagents, IVDs must be tested extensively to ensure that: 1) tubing materials do
cause contamination from one reagent to another, 4) tubing materials used to transport a sample from one device to anothe
various types of tubing in IVD instruments contain PFAS, but patient results meet product claims registered via medical reg
complexity of validation testing.
Electrical wire insulation: Insulation of electric wires on custom printed circuit boards, power cords and other internal wirin
parts withing the IVD device; and to ensure that the wire component does not present a heat source that can damage other
If PFAS are used in conjunction with electrical wire insulation, extensive testing will be required if substitute parts have a "lik
change to the longevity of parts occurs, 3) no software changes are required as a result of the part change and 4) conforma
parts with different electronic properties would be required, with a potential timeline of 10-15 years.

If the IVD products could not be placed on the market, Healthcare institutions would be required to make capital investment
addition, there are certain tests that are unique to the products, if those test were no longer available on our devices, patien
Over 650 million test assays per year in the EU are performed with affected devices. To the best of knowledge, if hospitals
commercially available and will not meet the high level of accuracy provided by the impacted devices. As a result, patient's
not allow lower-level performance products to be placed on the market, as such approval would be withdrawn if the adopted
would no longer be able to be placed on the market.

19. Intensive care devices and systems

• Valve coatings

The materials are indispensable mainly because of their resistance to aggressive media. More specifical
• Hoses, seals and other gas-carrying parts in medical devices must be permanently resistant to pure oxygen an
• In electrochemical sensors fluoropolymers are used as membranes in strongly acidic electrolytes (e.g. sulfuric a
materials must also withstand free oxygen radicals that would permeate all other plastics.
Furthermore, all electronic components contained in these products rely on semiconductors, the production of w
by a comprehensive PFAS ban. At the production plants, components made of fluoropolymers ensure durability,
products, including their spare parts.
Emissions:
No emissions of PFAS into the environment are to be expected from these products and the materials they conta
the present restriction proposal. A restriction is therefore not legally tenable. According to information from upstre
appropriate regulatory measures.
The products are in use for a very long time, in some cases over 20 years. Proper disposal at the end of life is en
interests of the circular economy, we would welcome an obligation to return waste to the manufacturer, but this h
the fluoropolymer components are thermally destroyed and converted into hydrogen fluoride, which is mineralize
case of deposition, the materials would behave chemically inert in the long term and would not cause emissions

Substitution possibilities:
According to the current state of knowledge, there will never be alternative materials that meet all the necessary
functional safety of the products, because human lives depend on it. Due to the high cost, fluoropolymer materia

Derogations:
Only a general and indefinite exemption for the use and manufacture of fluoropolymer materials in professional a
• Medical devices
• Medical gas supply systems
• Personal protective equipment (not only textiles) and
• Gas measuring devices
(in each case including accessories and spare parts) represents a minimum requirement, but one that is not suff
nevertheless introduced, it should at least be designed in such a way that the exemption is reviewed at the end o
The limit values for non-polymeric PFAS in articles must be based on the possibilities of chemical analysis in ord
measurement limit of the available analytical methods.
Such intensive care equipments like ventilators, anaesthesia devices and neonatal care incubators will no longer
anymore after a short period because spare parts could also not be placed on the market anymore. In a pandem

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