Proposed REACH restriction on
the manufacture, placing on the market and use of PFASs

Comments for Annex XV restriction report
(public consultation 22.03.2023 – 25.09.2023)

non-confidential attachment

Executive Summary

Our company is the world's leading provider of products and services for individuals with renal diseases of which around 3.9 million patients worldwide regularly undergo dialysis treatment. Through our network of clinics, we provide life-saving treatments around the globe. Our company is also the leading provider of dialysis products such as dialysis machines or dialyzers.

The REACH restriction proposed in January 2023 is intended to ban the production, placing on the market and use of all PFAS (per- and polyfluoroalkyl substances) as such or in mixtures and articles above certain tight concentration limits.

The scope of the restriction proposal includes more than 10,000 substances in total, thereby not distinguishing between potentially hazardous PFAS or non-hazardous PFAS. Especially the broadly used fluoropolymers are substances of low concern and do not cause environmental or human health hazards. This broad variety of PFAS both with regard to their properties and especially with regard to their uses make individual approaches necessary rather than a general restriction.

With regard to the restriction proposal, we express our concerns about the following aspects**:**

- Socio-economic: The health sector (here focusing on medical devices) helps to diagnose, to cure and to care. Lives and wellbeing of hundreds of thousands of patients depend on the availability of state-of-the-art medical products, each day and worldwide. Any missed, too small or too short exemption of a PFAS use in healthcare puts these lives in danger. It is not worth taking this risk, considering that already our impacted products are essential for **life-saving treatment of more than 2 million patients** globally.[13]

- Data gaps: Due to the broad relevance of PFAS in industry and the unprecedented large scope of the proposed restriction, current disclosure requirements via safety data sheets, SVHC declaration or other means are **fully insufficient** to build the basis for identification and evaluation of all relevant PFAS uses in time within this legislative process. [1, 2, 3] This weakness is also mentioned in the dossier.[1]

- Complexity: Few tight, detailed exemptions, as proposed in the dossier, cannot cover all relevant uses of PFAS in medical devices and pharmaceuticals and its supply chain. Initial screening of our processes and products [see below for details], as well as those reviews by other companies or expert groups of trade associations [see Annex II] already **identified several gaps and missing exemptions**: e.g. for numerous fluoropolymer components (like gaskets, gear wheels, valves, connectors, caps, packaging seals and safety membranes) of active and non-active medical devices, spare parts and manufacturing equipment/processes. With the current approach it can be expected that further relevant uses will be (unintentionally) banned with serious impact on the availability of these products

[1] Data gaps are also mentioned in the dossier but not considering the resulting potentially fatal socio-economic consequences in healthcare: "It is likely that some PFAS-using activities have not been included in the assessment, though the Dossier Submitters are confident that the main sectors of use are covered, based on literature review and the response to the CfE and the second stakeholder consultation (Annex A)." (Annex F)

in healthcare, i.e. putting patients' lives at risk. [1, 2, 3] **Much broader, generic exemptions for medtech/healthcare are needed.**

- No alternatives: PFAS, especially fluoropolymers like PTFE, PVDF, FKM or related polymer-blends, are often intentionally used due to their unique chemical/material properties. Alternatives are missing, would not fulfil required technical criteria or would have equal environmental properties.[2] Furthermore, substitution of materials in medical devices, pharmaceuticals and their manufacturing and supply chain is strictly regulated. So, existence of a possible general technical alternate is not yet sufficient for safe and legally compliance substitution in a specific medical product.[3] Any evaluation of alternatives and feasibility of substitution can only be component- and case-specific.

- Time & regulatory framework: The medtech sector is strictly regulated, has very high quality standards and is already today facing huge challenges, e.g., due to the implementation of new sectoral legislation (Medical Device Regulation (EU) 2017/745), shortage of capacities in R&D and regulatory affairs, and complex multi-tier supply chains. The transition and therefore the re-certification of all medical devices across the EU to this new MDR was prolonged to 2027/2028 due to limited Notified Body capacities and the risk of "shortages of medical devices needed for the smooth functioning of healthcare services" [6]. During this period, as long as medical devices are still registered under the former sectoral legislation (Medical Device Directive), significant material changes are not allowed anyway.

- Supply gaps: Medtech is also dependent from upstream suppliers, notified bodies and competent authorities. An uncoordinated sudden stop of supply of PFAS containing materials puts the supply of medical devices at risk. A phase-out of PFAS (if feasible at all) will require much more time, even in those few cases where an alternative might already exist from a technical point of view. An 18 months transitional period would not even ensure full disclosure of all PFAS uses in the complex multi-tier supply chains of medical devices. Even the proposed maximum exemption periods of 13.5 years would require that substitution starts immediately – impossible if non-PFAS alternatives are not yet available.

- Competition: The restriction puts high pressure only on EU-based manufacturers using fluoropolymers and distracts resources of R&D and other functions from innovation and from implementation of revised medical device legislation. This causes a significant disadvantage for the European MedTech and pharmaceutical industry at international markets and opposes efforts to increase the strategic autonomy of the EU. Exemptions for medical devices must also cover those manufactured inside EU for export under non-EU sectoral legislation (e.g. subject to US FDA approval instead of EU CE marking).

A forced change to non-PFAS alternatives or a no-derogation scenario would result in significant consequences, such as a permanent or long-lasting inability to manufacture critical medical devices and pharmaceuticals. This could lead to the discontinuation of life-saving technologies, medicines, and services, including procedures for renal replacement, apheresis, autoimmune therapy, and capital equipment used in related procedures.

While some detailed derogations for certain applications are proposed by the dossier submitters, many crucial medical applications remain disregarded or uncovered. If no drop-in alternative is available, as this is the case for all uses identified by us, or a PFAS is discovered in a medical device in future, the absence of an applicable derogation would adversely affect not only PFAS manufacturers and us, as medical technology producers and healthcare service provider, but

[2] see also [4]

[3] see e.g. [3] and sector-specific contributions in the public consultation for details of the regulatory framework, especially the lengthy and strictly regulated processes for qualification of new materials or suppliers and the steps needed to reach or update MDR certification.

especially millions of life-threatening ill patients throughout Europe and worldwide. The medical device and pharmaceutical sector is also dependent on its supply chain for alternative materials and components, which, when available, still need to pass lengthy regulatory approval processes.

Where available, a transition to non-PFAS medical technologies should be done in a **realistic timeframe** ensuring sufficient time to move to alternatives in a safe and controlled manner.

Considering the above-mentioned aspects and the critical function the healthcare sector has for the well-being and functioning of society there's need for **a full derogation for medical devices** and pharmaceuticals from the PFAS restriction including spare parts, intermediaries and the use of PFAS in the manufacturing facilities, processes and its upstream supply chain. Thereby, quality and continued access to essential medicines and medical technologies containing PFAS for patients and practitioners are guaranteed.

If this is not accepted, an additional review and safeguard clause after 13.5 years might stipulate that the continued need for such derogation is adequately assess without jeopardizing patients' life. This means that all time-limited exemptions if affecting the above-mentioned broad scope of medical devices and pharmaceuticals must include an explicit review and safeguard clause which ensures that such exemption never expires or is withdrawn without prior proper, holistic re-evaluation and confirmation that phase-out has been completed successfully. Everything else would result in significant consequences for patients' life.

PFAS relevance for Medical Devices

PFAS, including fluoropolymers, are used in medical technologies as they have a combination of properties that no other materials/chemicals have. They enable strength, durability, lubricity, biocompatibility, and processability which all allow state-of-the-art healthcare services and improve patient outcomes. PFAS can also be used during manufacturing or as part of drug-device combinations.

The low intrinsic hazard of fluoropolymers, the most important PFAS sub-group used in medical technologies, is important and proven by ISO standards [3]. Fluoropolymers have 45+ years of safe clinical use globally and are environmentally safe. Furthermore, medical technologies containing fluoropolymers are often disposed of as clinical waste and are incinerated, which adequately excludes emissions to the environment [9]. In accordance with Article 68(1) REACH stating that there must be an "unacceptable risk" to justify a restriction and because the PFAS Restriction is so wide, the focus should be on the inherent risk. The restriction starts from the premise that persistence is a hazard, but data shows that fluoropolymers' persistence on its own does not justify the need for specific risk-management measures. Fluoropolymers are not bioaccumulative, not mobile, and not toxic and therefore not SVHCs (Substances of Very High Concern) from a regulatory perspective [10].

Medical technologies help to diagnose, to cure and to care. Lives and wellbeing of hundreds, thousands and in some case millions of patients depend on the availability of state-of-the-art devices, each day and worldwide. While medical technologies with fluoropolymers are essential for life-saving treatment of huge patient groups, these polymeric PFAS uses represent only a minor share of the total use of PFAS.[4]

[4] 4% - 7% according to the restriction dossier, table 3

Alternatives to PFAS are often theoretical, and sometimes, only another type of PFAS would be used due to their superior performance and durability. Finding alternatives requires extensive assessments in material selection, including clinical trials, time (as the medical technology industry is dependent on upstream suppliers, notified bodies and competent authorities) and compliance with strict sectorial legislation.

Medical devices differ greatly with regard to the components they are being made of. Even routinely used devices may have hundreds and thousands of components which means that supply chains can be long and complex. Currently, there is no obligation to disclose whether products or materials provided by suppliers contain PFAS. That means that the medical technology sector is not and cannot be aware of all uses of PFAS, especially in complex medical devices with a lot of components and a sophisticated manufacturing process for these components itself. Given the extremely broad scope and low thresholds in the currently proposed restriction, existing data gaps cannot be quickly closed with the needed reliability by the sector, us as "downstream user" or by our suppliers. In case of a ban of a single component due to a missed identification of its PFAS relevance or a too tight or short derogation medical devices and related therapies might become unavailable for years.

While some detailed derogations for certain applications are proposed by the dossier submitters, many crucial medical applications remain disregarded or uncovered. If no alternative is available or a PFAS is discovered in a medical device in future, the absence of derogation would adversely affect not only PFAS manufacturers and medical technology producers but especially patients and practitioners throughout Europe and worldwide. The medical technology sector is also dependent on its supply chain for alternative materials and components, which, when available, still need to pass lengthy regulatory approval processes.

Example for the relevance of PFAS in complex medical technology

One example of concerned complex equipment are devices which are used to replace essential body functions in case of acute or chronic organ failure, keeping hundreds of thousands of patients alive worldwide. Our spot-checks and initial screening already identified more than a hundred different components, consisting of several different fluoropolymers. Uses include e.g. O-rings and parts of valves that must be biocompatible. Further parts which are common industry standard like batteries [5] or electronic components[5] certainly exist and will further increase the number of concerned parts.

Dialysis machines in scope of the proposed PFAS restriction (with EU-based production and containing fluoropolymer components) are in use for regular treatment of at least 1.9 million chronic dialysis patients globally (approx. every second patient worldwide). [13] Additional hundreds of thousands of acute patients with acute kidney failure are affected in the same way each year. These are life-threatening conditions, thus each of these more than 2 million patients' lives depend on uninterrupted availability and performance of these active medical devices and related spare parts.

Besides the above-described active medical devices, PFAS are also relevant for manufacturing and packaging of needed single-use disposables. Qualification of potential alternatives must be done for each concerned component individually, considering the specific technical and regulatory conditions. In the majority of components, a material change would also impact the tools used in production. This significantly increases the time and efforts required.

[5] See e.g. Annex A: "Although electronics is a separate use section, it should be noted that numerous electric medical devices such as scanners, screens etc. qualify as electronic devices. In electronics, PFAS is mainly applied in cables and wires, printed circuit boards and in (LCD) screens." (p.83)

Besides design of current and future devices, also the already phased-out products must be considered. Concerned active medical devices are investment goods, intended to be used in clinics and hospitals for several years. Thus, availability of spare parts for maintenance and repair of devices must be ensured for the whole use phase, i.e., approx. 10 years after stop of production.

Each change of the product design and related tools must follow strict rules and processes to comply with applicable quality, safety and regulatory requirements. Experiences with past (less complex and less numerous changes of materials) already indicate that a substitution of PFAS, if feasible at all, would take more than six years. Needed internal and external resources for technical qualification, bio-compatibility assessments and regulatory affairs for the required number of parallel substitution projects within such short timeframe are currently not available.

Furthermore, such analysis of potential alternative materials, design changes, change of tools etc. could only start after identification of a component as PFAS relevant. The active medical devices consist of thousands of components and materials, partially designed and manufactured in-house or, especially in case of electrical components, manufactured and supplied in a multi-tier supply chain. Due to the broad scope and low threshold values of the PFAS restriction, existing PFAS disclosure and resulting data is incomplete and mostly limited to obvious cases, e.g. if fluoropolymers are the specified material of a supplied mono-material component. But fluoropolymers in complex materials or components are currently not subject to disclosure requirements like Article 33 REACH. Consequently, the data on PFAS-containing/relevant materials and components is assumed to be highly incomplete, especially for complex electrical components of active medical devices and processes upstream the manufacturer of medical devices.

A complex medical device like a dialysis machine, however, may consist of around 5,000 items, some of them being complex sub-assemblies. A printed circuit board, for example, may consist of hundreds of components, each of them consisting of numerous materials, thereby relying on a multi-tier manufacturing and supply chain.

Experience with RoHS ("Restriction of certain Hazardous Substances" in electric and electronical devices by Directive 2011/65/EU) showed that generation of reliable and complete material compliance data takes years. RoHS restricts "only" 10 substances with a limit value of 100 – 1000 milligrams per kilogram. The REACH restriction proposition for PFAS anticipates the restriction of more than 10,000 substances with lower limit values of 0.025 – 50 milligrams per kilogram. In case of spare parts for products, availability of needed detailed PFAS data and willingness to invest in evaluation and re-design of components by concerned suppliers is highly questionable.

A forced change to non-PFAS alternatives or a no-derogation scenario would therefore lead to, for example, a permanent or long-lasting inability to manufacture critical medical technologies, and a discontinuation of life-saving technologies and services (e.g. procedures for renal replacement and capital equipment used in related procedures).

PFAS relevance for manufacturing of medical devices and pharmaceuticals

PFAS play a key role in the safe and efficient operation of manufacturing sites for both medical devices and pharmaceuticals. PFAS are used e.g. in manufacturing equipment (seals, coatings, valves, tubes, membranes, lubricants), auxiliary and operating material (e.g. PTFE lubricants for injection moulding) and protective clothing. They can keep their functionality even under extreme conditions like high temperatures or pressure or in contact with acids or leaches. Conditions which e.g. apply in sterilisation, formulation and filling facilities. The unique properties

of fluoropolymers are also often required to meet the high standards for hygiene and quality in the field of medical device and pharmaceutical products. Their properties make them essential for a safe and efficient operation of manufacturing sites, especially the wide variety of PFAS/fluoropolymer-based components like seals of pumps etc.

Further (very minor uses) include fluor-compounds in chemical analytics (laboratory setup and scale) and research & development.

Screening at some European production sites already confirmed the above-mentioned broad relevance. Even in a small production facility (<50 employees) hundreds of PTFE parts in production, sterilisation, filling, water purification etc. have been identified. Even more PFAS-relevant components or complex equipment are expected to be discovered in case of further research or disclosure by concerned equipment/component manufacturers. In case of our larger production sites, these number multiply up to several thousands. The majority of uses and components is currently not in scope of any exemption proposed by the dossier submitters.

Numerous regulations are in place for the operation of industrial manufacturing sites.[7] They also cover the use of perfluorinated compounds and products in manufacturing processes and the requirements for their impermeability. Regarding the latter, fluoropolymers play a crucial role. To obtain permission for operation, manufacturing sites have to fulfil strict and complex requirements including environmental authorization procedures as well as complex safety and quality requirements by product legislation (e.g. Good Manufacturing Practices, hygiene rules, process validation etc. to ensure product safety). Therefore, any change made to existing manufacturing sites requires a complex and time-consuming process and is not easy to realize. It goes without saying that, before such a process is being started, the existence of appropriate alternatives has to be guaranteed. Finding alternatives for a safe and efficient operation of industrial manufacturing sites with the same properties PFAS substances like fluoropolymers have, takes time and the results with regard to their effects on health and environment have to be proven before use.

Furthermore, the availability of spare parts for existing manufacturing sites has to be guaranteed in order to ensure their functionality.

Under all circumstances the operability of manufacturing sites for medical devices and pharmaceuticals has to be maintained. The availability of curing and life-saving high-quality products for patients has to be ensured. Last but not least, the economic impact a general ban of PFAS would have to be taken into consideration. The European Union openly strives for a strengthening of its economic resilience and for a reduction of being dependent on imports from third countries. A non-differentiated regulation of PFAS without taking into thoughtful consideration every aspect of the whole production and supply chain of medical devices and pharmaceuticals puts not only the life and well-being of patients, but also the economic strength and competitiveness of Europe’s economy at risk. European users will have to turn to third countries if PFAS are not regulated in a differentiated way with regard to their properties, with regard to their essentiality for the function of the society, with regard to their benefit-risk-assessment and with regard to timelines for the development of adequate alternatives. Furthermore, a regulation of PFAS should be aligned with other existing legislation and regulations.

The identified relevance in industrial processes and installations, especially in the chemical, pharmaceutical and medical devices sector and resulting critical situation for production is also confirmed by reviews provided by industry.[1,7,8]

Annex I – Overview on PFAS-relevance, lack of alternative, and required exemptions

Preliminary note:

The following table summarize prominent examples of PFAS (mostly fluoropolymers) which have been identified so far by us. The list…

- is **non-exhaustive**, i.e. the same or additional uses and issues are expected and partially already know to impact other healthcare sectors or medical technologies, e.g. extracorporeal heart and lung support like ECMO[6].
- is certainly lacking several more use cases due to the currently insufficient transparency on PFAS in complex products and multi-tier supply chains.
- is not able to provide detailed analysis of alternatives or monetarisation of socio-economic impacts given the extreme variety of use cases and the short timeline.
- is supplemented by references to supportive evidence (see Annex II).
- is sufficiently **representative** for our product segment due to the technology leadership and high market share of our company in this healthcare sector (e.g. up to 50% globally for concerned active medical devices).[13]
- is **consistent** with reviews by expert working groups in several sectors, including chemical industry[7], medical devices[8], batteries[9], machinery and equipment manufacturing[10] and further more[11] (see also Annex II)
- is consistent with several uses identified by the dossier submitter, while here putting more emphasis on the conditions, constraints and risks related to these uses in our healthcare sector.[12]
- is evaluating exemptions (proposed or missing) at a detailed level as done by the dossier submitters, notwithstanding the fact that only a **full derogation for medical devices** and pharmaceuticals from the PFAS restriction including spare parts, intermediaries, and the use of PFAS in the manufacturing facilities, processes and its upstream supply chain is able to ensure continued access to essential, life-saving medicines and medical technologies for millions of patients.
- is mentioning exemption periods as done by the dossier submitters, notwithstanding the fact that an **unlimited derogation** is needed. If this is not accepted: Any time-limited exemption must include an explicit review and safeguard clause which ensures that exemptions for the mentioned scope never expire or are withdrawn without prior proper, holistic re-evaluation. Everything else would jeopardizing patients' life.

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[6] ECMO (Extracorporeal Membrane Oxygenation) as a rescue measure is indicated, for instance, in the therapy support of severe acute respiratory distress syndrome (ARDS) characterized by refractory hypoxemia, or refractory cardiogenic shock. Active medical devices and related disposable products are used in intensive care for extracorporeal circulations. Their usual fields of application include heart-lung bypasses during acute open-heart surgery as well as temporary heart-lung assist for stabilization or recovery therapy of critically ill patients.

[7] VCI representing around 1,900 companies from the chemical-pharmaceutical industry and related sectors; In 2022 members employed approx. 550,000 employees.

[8] BVMed representing over 300 manufacturer, distributors and suppliers of the German medical technology sector; MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health, currently including members from more than 140 multinational corporation and more than 45 medical technology associations.

[9] RECHARGE is the advanced rechargeable and lithium batteries industry association in Europe, representing all steps of the battery value chain.

[10] VDMA: with 3,600 members the largest network of the machinery and equipment manufacturing industry in Germany and Europe

[11] BDI is the federation of German industries, with more than 100,000 large, medium-sized and small companies from all sectors of the manufacturing industry, which together employ more than eight million people.

[12] See e.g. Annex A: "Fluoroplastics (mainly elastomers) allow for protein-resistant and sterile filters, tubings, O-rings, seals and gaskets for kidney dialysis machines, and immuno-diagnostic instruments." (p.81), "Although electronics is a separate use section, it should be noted that numerous electric medical devices such as scanners, screens etc. qualify as electronic devices. In electronics, PFAS is mainly applied in cables and wires, printed circuit boards and in (LCD) screens." (p.83), "Membranes used for venting of medical devices: Hydrophobic/oleophobic membranes based on PTFE and PET with fluorinated C6 based side chain coatings are used for (sterile) venting of several medical devices, for example cell culture devices, analytical devices, blood tube systems for dialyzer systems, tube systems for eye surgery." (p.83)

PFAS relevance	Alternative available?	Technical constraints / conditions	Regulatory constraints/cond.	Socio-economic aspects	Exemption proposed in dossier / needed
ACTIVE MEDICAL DEVICES (E.G. DIALYSIS MACHINES AND RELATED WATER TREATMENT DEVICES)					
Use/component: ▪ numerous plastic components, which are or form a part of e.g.: adapters, bellow of valves, bushes, clutch housing, couplings, connectors, plugs and grips, filters, gear wheels, high-pressure pumps, closures, lockings, screws, magnetic valves, sensors, pipes and tubes, seals/O-rings, servo-valves, sliding foil, spouts, valve coatings. Used PFAS: ▪ fluoropolymers (especially PVDF, PTFE, FKM, and polymer blends containing PTFE, e.g. PA66+PTFE-CF10) NB: The given overview is preliminary. Anyhow, the number of affected components is already in the range of 200 with an estimated annual use of fluoropolymers in the range of 100 t/a.	**No** alternative available.	Exact technical specifications are **specific to the individual component**. Besides biocompatibility and safety (see left), chemical resistance (especially in case of contact to chemical disinfectants and acid dialysis liquids) and temperature resistance (e.g. to allow heat disinfection) are impacting the material section. Furthermore, the following constraints have been identified by experts: ▪ PTFE-blended plastic materials: UPTFE is used as additive due to the specific tribological characteristics (improve gliding properties / reduce friction). No replacement options have been identified so far. ▪ FKM: No replacement options have been identified by experts so far. In some cases, other materials have already been explicitly confirmed as inadequate (e.g. EPDM instead of FKM in water inlet valves). ▪ PVDF: required due to temperature resistance, processability into filter fabric, high mechanical stability in case of high temperatures, processability into very thin wall designs. ▪ PTFE: No other material available with needed chemical, thermic, mechanical & electrical properties ▪ Tools for injection moulding: Due differing shrinkage properties of other polymers, most tools must be modified or replaced in case of a material change (additional time & effort needed, after successful qualifi-cation of a PFAS-free material, if any)	▪ Products are strictly regulated by sectoral EU- and/or non-EU legislation (e.g. EU-MDD/MDR, FDA). ▪ The majority of identified components have contact to liquids (water, dialysis fluids) which are intended to be infused / come into contact with the patients' blood. Thus, compliance with strict quality, safety and biocompatibility requirements must be checked and confirmed for the current materials and any possible substitute. ▪ Suppliers of active medical devices (investment goods) are often legally bound to ensure supply of spare parts over a period of at least 10 years. ▪ Controlled design changes including testing and validation by the device manufacturer needed (Time and capacity constraints of expert functions due to numerous affected products in parallel).	▪ Dialysis machines in scope of the proposed PFAS restriction (with EU-based production and containing fluoropolymer components) are in use for regular treatment of at least **1.9 million chronic dialysis patients** globally (approx. every second patient worldwide).[13] ▪ Additional hundreds of thousands of acute patients with acute kidney failure are affected in the same way each year. ▪ These are **life-threatening** conditions, thus each of these more than 2 million patients' lives depend on uninterrupted availability and performance of these medical devices and related spare parts. ▪ Due to the high number of affected different components in these product groups, significant costs (multi-million EUR range) and efforts are expected for research & development of alternatives and subsequent design changes (if feasible). This will distract internal (R&D, regulatory affairs, manufacturing) and external (notified body, competent authorities) resources from innovations and other legal requirements (e.g. EU-MDR implementation, which is already facing serious resource constraints [6]).	**Additional** exemption needed – Only few uses or components might be currently covered by an exemption (tubes: **6c**; coating: **6j**) proposed in the dossier. Required **additional** exemption… ▪ must cover medical devices in scope of EU sectoral legislation (MDD/MDR) as well as those healthcare products/ components manufactured inside EU for export under non-EU legislation (e.g. US FDA approval). ▪ must have a broad and robust scope, as identification and detailed specification of hundreds of different known (and further currently unknown) uses is neither feasible nor enforceable. ▪ must provide a long timeframe - Based on experience with past substitution projects, the maximum of 13.5 years would trigger start of immediate phase-out actions of all concerned uses. This is conflicting with the still incomplete transparency on PFAS-relevance in industry and the outlined current lack of technical alternatives / missing substitution potential in our devices. ▪ must cover the whole supply and manufacturing chain. ▪ must also cover any related spare parts and materials for maintenance and repair.

PFAS relevance	Alternative available?	Technical constraints / conditions	Regulatory constraints/cond.	Socio-economic aspects	Exemption proposed in dossier / needed
Use/component: ▪ O-rings and silicone components with fluorinated surface treatment Used PFAS: ▪ fluorinated gases/plasma fluorination	**No** alternative available.	▪ This specialized technology has been developed to reduce friction / stickiness of specific components, ensuring medical device performance and safe use over long product lifetime. ▪ non-PFAS alternatives are currently fully unclear and certainly not yet qualified.	*Strictly regulated products to ensure patient safety; see previous line for details and further aspects.*	*Essential products for more than 2 million patients' lives; see previous line for details and further aspects.*	Unclear whether **6j** ("coating") might partially apply as definition/scope is quite **unclear**. An **additional** exemption with a broad and robust scope and a long timeframe is required (see details above).
Use/component: ▪ special lubricants based on PFPE ▪ special lubricants based on silicone oil and PTFE Used PFAS: ▪ perfluorpolyether oil (PFPE; low kilogram/year range) ▪ PTFE (low kilogram/year range)	**No** alternative available.	▪ The lubricants are used in manufacturing process to ensure required gliding properties a) when assembling specific components, or b) during the intended use of the medical devices ▪ So far, no adequate alternative has been identified. R&D by our supplier (who owns technology and know-how) is ongoing and open-ended.	*Strictly regulated products to ensure patient safety; see above for details and further aspects.*	*Essential products for more than 2 million patients' lives; see above for details and further aspects.* NB: No indication of emissions to the environment via wastewater; Currently no evidence of release up to given analytical evaluation thresholds.	**5s** ("lubricants use for safety") might partially apply, but the definition/ scope is quite **unclear**. An **additional** exemption with a broad and robust scope and a long timeframe is required (see details above).
Use/component: ▪ electrical and electronic components ▪ batteries/accumulators ▪ plastics materials with PTFE-containing flame retardants Used PFAS: ▪ unknown / tbc	**No** alternative available.	▪ Active medical devices consist of hundreds of electrical and electronic components which are often produced internationally in complex, multi-tier supply chains. ▪ Transparency on PFAS essentially needed in related manufacturing processes or contained in the finished electrical components is mostly lacking due to the broad scope and low threshold values of proposed PFAS restriction. ▪ All battery/accumulator types (except for lead acid) have already been identified as PFAS-relevant by the battery sector.[5] The same applies on electronics.[13] ▪ Downstream users are not in the position to phase-out PFAS in such components independently from the electronics & battery sector.	*Strictly regulated products to ensure patient safety; see above for details and further aspects (except for biocompatibility due to mostly missing contact to blood).*	*Essential products for more than 2 million patients' lives; see above for details and further aspects.*	**Additional** exemption needed, ensuring… ▪ a broad and robust scope ▪ coverage of the whole supply and manufacturing chain ▪ coverage of medical devices in scope of EU sectoral legislation (MDD/MDR) as well as those healthcare products/ components for export under non-EU legislation (e.g. US FDA approval). ▪ sufficient time for data collection / transparency ▪ sufficient time for downstream users like medtech to implement design changes (complex processes which can only start after completed re-design (if feasible at all) by the components manufacturer, i.e. the electronics & battery industry)

[13] Annex E, p.400 "The industry stakeholder consensus is that PFAS alternatives are not available for the electronic industry and if they are available in due time, the expected transition costs on average exceed €100 million and the expected transition times vary but are expected to be considerable (3-15 years)."

PFAS relevance	Alternative available?	Technical constraints / conditions	Regulatory constraints/cond.	Socio-economic aspects	Exemption proposed in dossier / needed
		▪ Furthermore, plastic grades containing flame retardants (required in many electrical parts for product safety reasons) have been identified as PTFE-relevant. [11] Transparency on such chemicals in complex electrical and electronic components and sub-assemblies is currently lacking.			NB: 5 – 10 years of implementation time is already needed by the battery manufacturer in cases where (from the component manufacturer's perspective) substitution is technically feasible. This does not yet take into account further time needed to bring these new components legally compliant and safe into the final, strictly regulated medical devices, and would not cover cases where alternatives are not available today.

PFAS relevance	Alternative available?	Technical constraints / conditions	Regulatory constraints/cond.	Socio-economic aspects	Exemption proposed in dossier / needed
NON-ACTIVE MEDICAL DEVICES (MOSTLY SINGLE-USE DISPOSABLES)					
Catheters and comparable products / related accessories, e.g. for peritoneal dialysis[14] <u>Use/component:</u> ▪ numerous connectors, adaptors and comparable components <u>Used PFAS:</u> ▪ PVDF (single digit tonnage range p.a.)	**No** alternative available.	Concerned uses are applications that make special demands and require high-performance materials which cannot be simply replaced by standard polymers. Example: The material of catheter connectors, which require very robust screw connections, is unchanged over the last roughly 30 years and has proven superior functionality and good acceptance by the patients. Relevant technical specification include:[15] ▪ High abrasion resistance: No particle formation or chip formation during screwing, ideal friction partner against itself and against polypropylene ▪ Inert, excellent chemical resistance to most aggressive substances and solvents and absence of released contaminates: No reaction with pharmaceutical solutions or irritation of skin ▪ Excellent mechanical strength and toughness: Thread and hose seat hold the hose ideally, no overtightening possible ▪ Wide range of rigid and flexible grades available: Barbs secure the screw connection against unintentional opening. No stress cracking.	▪ Products are strictly regulated by sectoral EU- and/or non-EU legislation (e.g. EU-MDD/MDR, FDA). ▪ The components have contact to liquids which are intended to be infused to the patients' body. Thus, compliance with strict quality, safety and biocompatibility requirements must be checked and confirmed for the current materials and any possible substitute. ▪ Sterile products - Compatibility with needed sterilization mode needed. ▪ Controlled design changes including testing and validation by the device manufacturer needed (Time and capacity constraints of expert functions due to numerous affected products in parallel).	▪ Peritoneal dialysis is a life-saving treatment mode applied by more than **400,000 end-stage renal disease patients** globally [12]. Non-availability of required regular treatments is fatal. ▪ The used material is very well accepted by patients in daily usage and nearly no complaints on malfunction are reported. Thus, substitution (if feasible at all in future) is expected to result in reduced quality of care, less patient acceptance and/or reduction of shelf-life, i.e. more waste and more costs and more burden on patients and the health care system. ▪ Due to the high number of affected different components, significant costs and efforts are expected for research & development of alternatives and subsequent design changes (if feasible). This will distract internal (R&D, regulatory affairs, manufacturing) and external (notified body, competent authorities) resources from	**6c** might be relevant, but **not sufficient** as scope and timeline are expected to be too tight. Required **additional** exemption… ▪ must cover medical devices in scope of EU sectoral legislation (MDD/MDR) as well as those healthcare products/ components for export under non-EU legislation (e.g. US FDA approval). ▪ must have a robust scope, also covering comparable components and accessories that are neither "tubes" nor "catheters", e.g. separate adaptors for catheters. ▪ must cover the whole supply and manufacturing chain. ▪ must provide a longer timeframe - The proposed time-limited exemption 6c would trigger start of immediate phase-out. This is conflicting with the missing substitution potential which is already outlined in Annex E of the dossier (p.319)[16] Since the manufacturers of the basic materials have not yet presented any alternatives, medical technology must find these itself. This development and validation of new materials and the following country approvals and regulatory issues take much more time.

[14] Peritoneal catheters are implanted into the peritoneum. To connect it with the sterile fluid bags, required for daily treatment, these catheters are equipped with connectors. Such catheters remain implanted up to ten years, thus, a high-performance polymer is needed at meets all requirements regarding long-term reliability, mechanical resistance, safety and biocompatibility.

[15] It is precisely these listed properties of the polymers that are needed for these medical devices, since sterilization, storage and use by the patient place a high load on the material. Manufacturers must ensure that the material can withstand these stresses over the shelf life (up to 5 years) and that the patient can use the medical device safely. Thus, other materials fail because of shortcomings related to biocompatibility, sterilization methods, stress cracking, no abrasion resistance, poor aging resistance, or being also high-performance PFAS planned to be restricted (PTFE, FKM, FFKM, POM XX TF natural, PEEK-xxxx (CFXX+TF10), PA66 GFXX TF15)

[16] "evidence is [sufficiently strong] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [tubes and catheters] and that the substitution potential is [low]."

PFAS relevance	Alternative available?	Technical constraints / conditions	Regulatory constraints/cond.	Socio-economic aspects	Exemption proposed in dossier / needed
		▪ Excellent ageing resistance: Components are safely applicable beyond the MDH ▪ High temperature capabilities: continuous use service temperature up to 150°C/302°F allows steam sterilization ▪ High purity: biocompatible ▪ Resistance to UV and nuclear radiations: sterilization via radiation possible ▪ Low permeability to most gases and liquids: no swelling ▪ Easily melt-processed by standard methods of extrusion/ moulding		innovations and other legal requirements (e.g. EU-MDR implementation, which is already facing serious resource constraints [6]).	
bloodlines, cassettes, other accessories and tubing for dialysis treatment (medical devices) <u>Use/component:</u> ▪ sterile membrane / protective transducer membrane[17] <u>Used PFAS:</u> ▪ fluoropolymers (ePTFE, PTFE)	**No** alternative available.	▪ In PD, the specific membrane is required to provide air in a safely manner to the dialysis machine (PD cycler), i.e. must filter contaminants and viruses in line with the specification and safety requirements. ▪ In HD, the specific, hydrophobic membrane is required to protect the machine from contamination by blood via the pressure tube while permitting exact blood pressure measurement during treatment. ▪ Thus, a specific combination of permeability and repellent features must be provided by the membrane ▪ Compatibility with applied sterilisations methods and sufficient shelf-life needed. ▪ Variations must not impede the product safety or disposable-machine interface (i.e. correctness of blood pressure measurement during treatment). ▪ So far, actions mostly focused on technical aspects and compliance with POP (avoiding traces of regulated PFOA substances).	▪ Products are strictly regulated by sectoral EU- and/or non-EU legislation (e.g. EU-MDD/MDR, FDA). ▪ Compliance with strict quality and safety requirements must be checked and confirmed for the current materials and any possible substitute. ▪ Sterile products - Compatibility with needed sterilization mode needed. ▪ Controlled design changes including testing and validation by the device manufacturer needed (Time and capacity constraints of expert functions due to numerous affected products in parallel).	▪ Concerned medical devices are an **essential** material for life-saving treatment of dialysis patients. ▪ The products are specific to the used dialysis machine, i.e. cannot be easily substituted by another product of the same product group. ▪ Based on our European production volume, life-saving treatment of >>300,000* patients is affected.	**5cc** (not yet confirmed) or **6c** (unclear whether all identified uses are in scope of "tubes") might be relevant, but **not sufficient** due to their unclear scope and timeline. Required exemption… ▪ must provide a robust scope (see weaknesses above) ▪ must cover medical devices in scope of EU sectoral legislation (MDD/MDR) as well as those healthcare products/ components manufactured inside EU for export under non-EU legislation (e.g. US FDA approval). ▪ must provide a long timeframe - Based on experience with past substitution projects, the maximum of 13.5 years would trigger start of immediate phase-out actions of all concerned uses. This is conflicting with the still incomplete transparency on PFAS-relevance in industry and the outlined current lack of technical alternatives / missing substitution potential in our devices. ▪ must also cover the whole supply and manufacturing chain.

[17] Concerned uses are also described in Annex A (p.83)

PFAS relevance	Alternative available?	Technical constraints / conditions	Regulatory constraints/cond.	Socio-economic aspects	Exemption proposed in dossier / needed
liquid dialysis concentrates and disinfectants (medical devices) Use/component: ▪ packaging (O-ring seal, ball seal of valve) ▪ gas venting membranes Used PFAS: ▪ fluoropolymers (FKM, PTFE, ePTFE)	**No** alternative available.	▪ Standard material for high performance applications to be replaced. ▪ Safety, storage and chemical stability (in case of concentrates: to acids and salts; in case of disinfectants: extreme pH, chlorine compounds and peroxides).	▪ Products are strictly regulated by sectoral EU- and/or non-EU legislation (e.g. MDD/MDR, FDA). ▪ Compliance with strict quality & safety require-ments must be checked and confirmed for any possible substitute. ▪ Dialysis concentrates have contact to the patients' blood. Thus, the concerned components and any possible sub-stitute must also fulfil strict biocompatibility. ▪ Some packaging versions are subject to additional type-approval acc. to ADR provisions for transportation of dangerous goods.	▪ Concerned liquid dialysis concentrates are an **essential** medical device for regular life-saving treatment of dialysis patients. ▪ Production and filling capacities are limited and specialized thus related amounts could not be shortly replaced by other products or packaging types. [14] ▪ A short-term interruption of supply would impact >>10,000* patients. ▪ Concerned disinfectants are applied in clinics to ensure safety and hygiene during regular life-saving treatment of dialysis patients.	**Additional** exemption needed - This use is not covered by **6n** (because the devices do not require sterilization due to their composition and low pH value) and probably not covered by **6l** (because the concerned packaging is mostly "non-PCTFE based"). **5cc** (not yet confirmed) might be relevant for the membranes only, but **not sufficient** due to the limited scope and timeline. An additional exemption… ▪ must provide a robust scope (see weaknesses above) ▪ must cover medical devices in scope of EU sectoral legislation (MDD/MDR) as well as those healthcare products/ components manufactured inside EU for export under non-EU legislation (e.g. US FDA approval). ▪ must include a reasonable timeframe (in the range of min. 13.5a). ▪ must also cover the whole supply and manufacturing chain.
synthetic adsorber for apheresis (medical device) Use/component: ▪ ventilation membrane Used PFAS: ▪ fluoropolymer[18] (membrane coating)	**No** alternative available.	▪ Hydrophobic barrier in the ventilation of device's housing ▪ To ensure product and patient safety by retaining possible contaminations from the inner part of the product (and thus patient's blood) ▪ Must meet the applicable conditions for sterilisation, storage (aging) and use (case-specific evaluation needed; investigation started)	▪ Products are strictly regulated by sectoral EU- and/or non-EU legislation (e.g. EU-MDD/MDR, FDA). ▪ Compliance with strict quality, safety and biocompatibility requirements must be checked and confirmed for any possible substitute. ▪ Controlled design changes incl. testing/ validation by device manufacturer needed	▪ The concerned device is intended for whole blood lipoprotein apheresis to treat patients suffering fr. severe lipid metabolism disorders. ▪ Even if the total number of affected patients* (and thus also the amount of used fluoropolymers) might be low compared to the number of dialysis patients, the individual **medical value** for each patient and thus the socio-economic value is high. ▪ Anyhow, limited capacities for comprehensive material qualification and certification (see above/ [6]) may cause end of business for products with low market volume.	**5cc** (not yet confirmed) would apply and is needed. The **adjusted** exemption… ▪ must include a reasonable timeframe (exceeding 13.5a). ▪ must also cover the whole supply and manufacturing chain.

[18] Contains traces of "PFOA or any of its salts" and "PFOA-related compounds" in line with the provisions of the related entry of Annex I POP Regulation EU 2019/1021.

PFAS relevance	Alternative available?	Technical constraints / conditions	Regulatory constraints/cond.	Socio-economic aspects	Exemption proposed in dossier / needed
synthetic broad-spectrum immunoadsorber (medical device) <u>Use/component</u>: ▪ specific processing material & ligand for adsorber material <u>Used PFAS:</u> ▪ Trifluoroacetic Acid (CAS 76-05-1; gram/year range)	**No** alternative available.	▪ Selective ligand and medical adsorber materials **are high specialized**; development of changed material would be case-specific. ▪ TFA is used in manufacturing of the ligand and remains in the raw material in a concentration of approx. 10% w/w until final production of the adsorber material. ▪ Currently no alternative counter ions are known to be able to substitute TFA [supplier consultation in 2023] NB: TFA is no intended part of the finished medical device, except for accepted trace-residues, if any.	▪ Products are strictly regulated by sectoral EU- and/or non-EU legislation (e.g. EU-MDD/MDR, FDA). ▪ The final adsorber has contact to blood/plasma. Thus, compliance with strict quality, safety and biocompatibility requirements must be checked and confirmed for the current materials and any possible substitute (repetition of performance tests / verification activities etc.).	▪ The concerned device is used in immunoadsorption, an extracorporeal blood purification procedure, by which antibodies are quickly and selectively removed from the patient's plasma. ▪ It is a drug-free option for patients **suffering clinical disorders caused by auto-antibodies** which do not respond to medicinal therapy. ▪ Even if the total number of affected patients (and thus also the amounts of used fluoropolymers) might be low compared to the millions of dialysis patients, the individual medical value and thus the socio-economic value are high. ▪ Without TFA-based production, the concerned medical device and thus the related treatment are currently <u>not possible</u>.	**Additional** exemption needed – This use and an applicable exemption are currently missing in the dossier. The additional exemption… ▪ must cover the whole manufacturing and supply chain of concerned use. ▪ must provide a long & robust timeframe, considering the current lack of alternatives and the long development and approval time for design changes, if feasible at all in future (i.e. exceeding 13.5 years)

PFAS relevance	Alternative available?	Technical constraints / conditions	Regulatory constraints/cond.	Socio-economic aspects	Exemption proposed in dossier / needed
MANUFACTURING EQUIPMENT FOR MEDICAL DEVICES AND PHARMACEUTICALS					
<u>Use/component:</u> ▪ Thousands of seals, coatings, valves, tubes, membranes, etc. ▪ lubricants (e.g. perfluoropolyether/ PTFE grease for injection moulding) ▪ laboratory chemicals for R&D, QC etc.[19] <u>Used PFAS:</u> ▪ perfluoropolyether ▪ fluoropolymers (e.g. PTFE, PVDF, FKM etc.) NB: Further PFAS-relevant uses can affect HVACR and other on-site infrastructure, e.g. heat/power stations.	**No** alternative available.	▪ Case/use specific evaluation needed; technology and know-how is mostly owned by the related original equipment manufacturer. ▪ Short- or mid-term replacement not feasible due to lack of adequate alternative and specialized staff. ▪ Machines and plants are built to last for decades, thus reliability, performance and availability of spare parts are key.[1, 8]	▪ Subject to strict requirements related to medical device quality / Good manufacturing practises (pharmaceuticals), e.g. hygiene rules, process validation etc. to ensure product safety and compliance. ▪ Manufacturing sites have to fulfil strict and complex requirements including environmental authorization procedures (e.g. German BImSchG, AwSV, TA Luft).	▪ Interruption of the manufacturing process impacts the supply of concerned medical devices and pharmaceuticals. ▪ In our case, these are an essential material for life-saving treatment of dialysis patients and other critically ill patients. ▪ More than **2 million patients' life** depend in total on uninterrupted availability and performance of these medical devices and related spare parts, or are at sever risk in case of interrupted production. ▪ Due to the high number of affected different components, significant costs and efforts are expected. This will distract internal and external budget and resources e.g. from innovations. ▪ Lack of materials/components to ensure adequate maintenance and repair would result in higher failure rate, elevated waste amounts and earlier shut-down and replacement of equipment. Replacement costs of existing facilities might reach the multi-millions EUR range.	**Additional** exemption needed, which… ▪ must ensure continued use, maintenance and repair ▪ must cover the whole manufacturing and supply chain of pharmaceuticals and medical devices in scope of EU sectoral legislation (e.g. MDD/MDR) as well as those healthcare products/ components for export under non-EU legislation (e.g. US FDA appr.). ▪ must provide an unlimited or very long timeframe considering: * sufficient time for data collection/ transparency * the development and investment cycles of concerned facilities * the socio-economic value of concerned finished products, * that technology and know-how is mostly owned by the related original equipment manufacturers while subsequent validation and approval tasks are mostly needed at individual site-level by concerned downstream sectors like medtech.

* Confidential business information - exact numbers available on request.

[19] Use of PFAS chemicals in R&D and laboratory applications, e.g. quality control and analytics (low kilogram range) are not described in detail, assuming that these uses and related upstream supply chain are exempted as "scientific research and development".

Annex II – Reference and Supportive Evidences

[1] BDI, 23.04.2023: „PFAS-Beschränkung Bewertung des Beschränkungsvorschlages"; retrieved at: https://bdi.eu/artikel/news/pfas-beschraenkung-bewertung-beschraenkungsvorschlag [20]

[2] Bundesverband Medizintechnologie, 25.05.2023: „BVMed-Stellungnahme zum Anhang XV Report zur Beschränkung der Herstellung, des Inverkehrbringens und der Verwendung von Per- und Polyfluoralkylsubstanzen (PFAS) unter der Verordnung (EG) Nr. 1907/2006 (REACH)."; retrieved at: https://www.bvmed.de/download/bvmed-stellungnahme-zur-pfas [21]

[3] MedTech Europe, 07.09.2023: "MedTech Europe Position on the Proposal for A REACH Universal PFAS Restriction" [22]

[4] Nationaler Wasserstoffrat, 01.02.2023: „Stellungnahme: Auswirkung des Verbots der per- und polyfluorierten Chemikalien (PFAS)"; retrieved at: https://www.wasserstoffrat.de/fileadmin/wasserstoffrat/media/Dokumente/2023/2023-02-01_Stellungnahme_PFAS-Verbot.pdf

[5] RECHARGE, April 2023: "Application for derogations from PFAS REACH restriction for specific uses in batteries – First submission"; retrieved at: https://rechargebatteries.org/wp-content/uploads/2023/06/RECHARGE-FIRST-submission_.pdf [23]

[6] REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical device

[7] VCI, 30.08.2023: „VCI-POSITION on the REACH Restriction proposal for PFASs"; retrieved at: https://www.vci.de/ergaenzende-downloads/vci-position-pfas-restriction-englvers.pdf [24]

[8] VDMA, 23.05.2023: „Position papier: PFAS restriction under the REACH Regulation"; retrieved at: https://www.vdma.org/viewer/-/v2article/render/79600192 [25]

[9] Aleksandrov et al., 2019: "Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas", Chemosphere

[10] Stephen H. Korzeniowski et. al, June 2022: "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers", Integrated Environmental Assessment and Management — Volume 19, Number 2—pp. 326–354

[11] European material supplier (name confidential), 13.09.2023: Technical datasheet

[12] Company's patient survey (year 2021); available on request

[13] Company's Annual report 2022

[14] Company's Internal risk assessment, 2022 (confidential)

[20] BDI is the federation of German industries, with more than 100,000 large, medium-sized and small companies from all sectors of the manufacturing industry, which together employ more than eight million people.

[21] BVmed is representing over 300 manufacturer, distributors and suppliers of the German medical technology sector

[22] MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health, currently including members from more than 140 multinational corporation and more than 45 medical technology associations.

[23] RECHARGE is the advanced rechargeable and lithium batteries industry association in Europe, representing all steps of the battery value chain.

[24] VCI representing around 1,900 companies from the chemical-pharmaceutical industry and related sectors; In 2022 members employed approx. 550,000 employees.

[25] VDMA: with 3,600 members the largest network of the machinery and equipment manufacturing industry in Germany and Europe