September 25, 2023

To: European Chemicals Agency

Re: PFAS Restriction Commentary

Dear ECHA Consultation Committee,

Integer manufactures complete medical devices as well as medical device components for many of the largest medical device companies in the world. Integer also manufactures batteries ranging from small implantable medical batteries to large industrial lithium batteries. Fluoropolymers such as PTFE, FEP, ETFE, ePTFE, and PVDF are all integral materials across our product portfolio. Integer, as well as the medical device and battery sectors as a whole, will be heavily impacted by a restriction of PFAS that includes fluoropolymers. Therefore, Integer would like to submit the following commentary on the proposed PFAS Restriction.

Our first request would be that fluoropolymers are excluded from the scope of the restriction. Fluoropolymers have a range of properties that make them extremely beneficial to society and these materials have become ubiquitous. They are extremely inert, highly chemical resistant, nearly frictionless, and very biocompatible, which is why they play a major role in our medical devices. Fluoropolymers are also a vital constituent in our battery and capacitor products. There are numerous examples where fluoropolymers play important roles in the fit, form, function and/or even safety of these products. A restriction on fluoropolymers will have far-reaching impacts on society that could set back quality of life improvements not only on medical devices, but also on medical procedures for many years or even decades. Fluoropolymers are undeniably useful and are arguably the safest of all PFAS, so some consideration should be made for exempting them from the broader PFAS restriction.

Additionally, it should be noted that both waste medical devices and waste battery products are regulated under other EU regulations. These regulations could be amended to ensure that resulting fluoropolymer waste is properly disposed of. For example, medical device waste is biohazardous and is often sterilized by incineration. The current regulations could be expanded to ensure fluoropolymers in medical devices are fully incinerated before disposal as well. Similar emission laws could be placed on fluoropolymer manufacturers to limit PFAS emissions during production. This sort of approach would allow the full benefit of fluoropolymers to continue in certain products while ensuring PFAS emissions to the environment are minimized.

If fluoropolymers must be included in the scope of the PFAS regulation, then Integer requests that our products utilizing fluoropolymers be provided derogations. Fluoropolymers are utilized in our devices because their unique characteristics are fundamental to their function. There are no other materials that we are aware of that could be considered direct alternatives for most of our fluoropolymer uses. Finding and employing alternatives, if even possible, will take many years due to the amount of testing and approvals required in the medical device industry. Therefore, Integer requests derogations of the longest term for all of our products listed below:

[redacted]

IMPLANTABLE MEDICAL DEVICES

- Stents
- Hernia meshes
- Implantable batteries
- Implantable Pulse Generators (IPG's) and components
- Leads
- Feedthroughs

INVASIVE MEDICAL DEVICES

- Guidewires
- Introducers
- Catheters and other medical tubing
- Hypodermic tubing / Hypotubes
- Mandrels
- Other associated instruments and tools

BATTERIES AND CAPACITORS

- Lithium primary medical batteries
- Lithium primary industrial batteries
- Capacitor cells and packs

Many of our medical devices use components made directly of fluoropolymers, but fluoropolymer coatings are also very common. Often metals in medical devices are coated with a fluoropolymer layer to reduce friction. For example, a guidewire coated in PTFE is less likely to cause damage to a patient's interior artery wall compared to an uncoated wire. For similar reasons, hypodermic tubes, introducers, mandrels, and other instruments and tools are often coated to improve functionality and patient safety. A large group derogation for "coated medical devices" would be much appreciated and would ensure all of these life-saving, coated medical devices can continue to be produced while alternative materials are explored.

It was noted that a derogation for implantable medical devices was already included in the proposal. This covers many of our products, however, hernia meshes was specifically excluded from this derogation description. Integer would like for this exclusion from the derogation to be reconsidered as fluoropolymers play a valuable role in implantable meshes. Making implantable meshes with fluoropolymers helps prevent body tissues from adhering to the mesh device which can result in tearing. Since fluoropolymers can be crucial to the safe use of these devices, they should be included in the implantable devices derogation.

Lithium primary batteries should also be provided a derogation. Integer's position on this is in alignment with RECHARGE. Fluoropolymers are used as electrode binder materials within all of Integer's industrial lithium batteries. Binder materials are important in the function and manufacturability of these batteries, and fluoropolymers are ideal due to their mechanical, thermal, and dispersive properties as well as their electrochemical stability. These materials will not be easy to replace, and time will be required to explore new chemistries. The modern world is dependent on batteries, and fluoropolymers have aided in their advancement. Our large industrial batteries are heavily used by the oil and gas industry, the military, and in

environmental surveying equipment. A derogation is needed to ensure these lithium batteries are not sorely impacted.

In summary, Integer believes that fluoropolymers should be excluded from the scope of the PFAS restriction. They present less risk to the environment and human health than non-polymer PFAS while also being the most beneficial to society. The medical device and battery products discussed in this commentary depend on these materials. Integer requests that our use of fluoropolymers in our medical device and battery products be provided derogations to ensure sufficient transition times to find and implement alternatives.

For specific information please refer to the attached appendices with commentary corresponding to specific ECHA consultation questions. Thank you for your consideration.

Sincerely,

Chris Tatum
Product Compliance Engineer
EHSS Center of Excellence
Integer

APPENDIX

Specific Information Requests

1:
Sectors and (sub-)uses: Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.

Integer's commentary applies to our medical device and battery products that we manufacture. These would pertain to the "Medical Devices" and "Energy" sectors listed in Table 9 of Annex XV. We would like to provide additional information on some sub-sectors up for derogation reconsideration as well as propose new sub-sectors be included in the derogations. Our comments include specific fluoropolymer use and function within these products as well as a discussion on the feasibility of alternatives. Also included is commentary on disposal of these products.

Our comments apply to these specific sectors and uses:

Medical devices:

- Implantable medical devices, specifically hernia meshes
- Other coating applications, with specific product listing.

Energy:

- Lithium primary batteries.

3:
Emissions in the end-of-life phase: With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.

Medical devices, once used, are considered biohazardous waste and disposal of such products is already regulated. The waste must be sterilized before disposal to remove infectious pathogens and is often incinerated to achieve this. In addition to destroying biohazardous pathogens, incineration has shown to be an effective method of destroying fluoropolymers like PTFE as well. A 2019 study released in Chemosphere by K. Aleksandrov et al. states that PTFE can be transformed into hydrofluoric acid through PTFE combustion. Carbon tetrafluoride, the simplest perfluorocarbon, decomposes at 1400 °C. Regulations can be implemented to ensure that all fluoropolymer-containing medical devices are incinerated before disposal to prevent PFAS from being released into the environment.

Similarly, battery waste is regulated under WEE, Directive 2006/66/EC and the new European Battery Regulation. While these regulations focus on heavy metals, the scope of these regulations could be expanded to include fluoropolymer recycling or disposal requirements as well. As recommended for medical device waste, incineration could be a required method of disposal for the fluoropolymer component materials. A disposal cost will incur that could be absorbed by consumers and manufacturers, but ultimately regulating fluoropolymer waste on a per-product type basis would allow critical fluoropolymer applications to remain in use while meeting the goal of preventing PFAS emissions to the environment.

6:

Missing uses – Analysis of alternatives and socio-economic analysis: Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:

a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.
b. The key functionalities provided by PFAS for the relevant use.
c. The number of companies in the sector estimated to be affected by the restriction.
d. The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.
e. For cases in which **alternatives are not yet available**, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.
f. For cases in which **substitution is technically and economically feasible** but more time is required to substitute:
    i. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);
    ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
    iii. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);
    iv. information on the benefits for alternative providers.
g. For cases in which **substitution is not technically or economically feasible**, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

Lithium primary batteries should also be provided a derogation within the PFAS restriction because fluoropolymers are crucial to the function and safety of these batteries. PTFE is currently used as the electrode binder material within all of Integer's lithium-oxyhalide batteries. Due to its unique properties, PTFE is the only known material that can be used as a binder to produce this type of battery.

PTFE consists of very long polymer chains that effectively entangle the cathode material particles so that these particles become bound together without chemically reacting with the binder. PTFE is extremely chemically resistant and does not react at all with the highly oxidizing electrolyte liquids (thionyl chloride and sulfuryl chloride) over a very wide temperature range. PTFE is physically stable and does not melt or soften at the very high temperatures at which the batteries operate (up to 200°C). A binder material must meet all of these conditions in order to function safely.

There are no alternative binder materials currently known that meet all the physical, chemical, and thermal requirements. Any alternative would need to be inert to highly oxidizing electrolytes and would need to remain physically unchanged through the entire operating temperature range of -55C to over +200C. If these parameters are not met then there is high risk that the binder will decompose, releasing the cathode particles and causing very hazardous shorting within the batteries.

Integer is not aware of any research being done to design alternative compositions for these battery applications. Even if alternatives did exist today, rigorous testing would need to be conducted to ensure that the new binder material would remain physically and chemically unchanged under the conditions in which these batteries operate. Testing would need to be conducted over the wide operating temperature range and the battery products would need to undergo shock and vibration testing. More importantly, some of these batteries remain in use for over 10 years once deployed. Testing would need to be conducted to demonstrate that the alternative binder would remain stable in the electrolytes for more than ten years.

Even if a non-PFAS binder material existed today, it would require the longest derogation duration to prove feasibility and safety of these products. Using an alternative material that has not been thoroughly tested could severely impact the performance of the batteries. And when dealing with such high-energy batteries, battery failures can possibly lead to severe injuries or even death. Therefore, a derogation is requested for our lithium primary battery products to ensure new designs are implemented as safely as possible.

Other missing uses Integer would like to submit are for specific product types listed below that we manufacture using fluoropolymer materials. These product types were not mentioned specifically within the proposed restriction, but fluoropolymers are essential to their function and derogations should be considered. However, the typical application of fluoropolymers for these devices is as a coating and would fall under the “other coating applications” sub-use derogation. Therefore, further information is provided in the next section covering derogations marked for reconsideration.

- Guidewires
- Introducers
- Hypodermic tubing / Hypotubes
- Mandrels
- Other associated instruments and tools

7:

Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis: Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.

A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.

To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.

Hernia meshes was specifically excluded from implantable devices derogation description and marked for reconsideration. Integer would like for this exclusion from the derogation to be reinstated because fluoropolymers play a valuable role in implantable meshes. PTFE, ePTFE, irradiated PTFE, FEP, and PVDF are the common fluoropolymers used in hernia meshes. Lightweight meshes have been used for internal repairs for decades now and different materials have shown to have various inherent complications. Polypropylene and polyester meshes have a low risk of infection, however, these have a high risk of adhesion. In contrast, fluoropolymers, while having a higher risk of infection, have a very low risk of adhesion formation and can be utilized to mitigate this particular negative outcome. Depending on the conditions and location of the repair, a surgeon may often choose one material over another. Many modern meshes are actually composites incorporating multiple polymers with the aim to leverage the benefit of each material. Since fluoropolymers can be crucial to reducing adhesion risks in these vital medical devices, they should be included in the implantable devices derogation to ensure sufficient time to explore alternatives.

In stark contrast to many non-polymer PFAS which are known to be hazardous, fluoropolymers like PTFE are extremely biocompatible and are intentionally introduced into the body regularly through medical devices. Integer manufactures a plethora of medical devices, and a portion of our devices get coated with fluoropolymers to attain a set of desired properties. For example, a guidewire coated in PTFE is less likely to cause damage to a patient's interior artery wall compared to an uncoated wire. For similar reasons, hypodermic tubes, introducers, mandrels, and other instruments and tools are often coated with fluoropolymers to improve functionality and patient safety. Integer therefore highly encourages that derogations are reconsidered and granted for all coating applications within medical devices.

Many desirable properties for medical devices are present in fluoropolymers like PTFE, PFA, and ePTFE. The table below lists some of these material attributes and compares them against some of the proposed replacements like PEEK, silicone, and polyurethane. It is evident that while other materials exhibit some of these properties, most of these desirable traits are present in the incumbent materials being used.

Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistan	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

When considering alternatives, the Appendix to Annex E.2 lists many materials as alternatives to fluoropolymers for medical devices. Integer's cognizant team has reviewed the list and decided to comment on the list of "alternatives" identified, specifically for the medical devices tab. Comments for each particular material is noted in the table at the end of this section. In summary, many materials listed are simply not suitable substitutes for the particular applications in which fluoropolymers are currently utilized within our medical devices.

When considering the time required to implement alternatives, the qualification/validation for any alternative material could only start once a suitable substitute is identified. Identifying a substitute and determining its feasibility could take from 18 up to 24 months; lab sample review, pre-feasibility and feasibility studies would need to be executed through each iteration (rarely the first selection works as a "drop-in" substitute). Once the appropriate substitute is chosen, validation activities include Process Characterization, Operational Qualification, Product Qualification need to be executed, extending the timeline for another 12-18 months. Once Integer has validated a replacement, then our customers need to perform their own qualifications and submit regulatory approvals, adding 18-24 more months to the project timeline; worst case scenario you are looking at ~72 months (6 years) from beginning to end to have a suitable qualified and regulatory approved substitute material. Additionally, switching to a new material/process/technique would make Integer equipment/investment redundant or obsolete and would also results in more expenditure and, if new equipment needs to be introduced, Installation Qualification (IQ) and Software Validation (if applicable) would be necessary, adding another ~3-6 months to the effort.

Integer has five manufacturing sites that perform fluoropolymer coatings by different techniques: Reel-to-Reel, Electrostatic Spray, Dipping and Film Casting; these capabilities mean a multi-million USD investment not only in equipment but also in facilities, utilities, manpower and resources. Two of these coating facilities manufacture guidewires within the EU and would be severely impacted by a ban on these types of coatings. For guidewires in particular, coating with PTFE is standard practice and these medical devices are not currently covered by an existing derogation. A derogation group for other coating application is needed to ensure that these life-saving medical devices can continue to be produced while alternative materials are explored.

Substance name	Uses	Comment
Hydrocarbon polymers (Polyethylene : UHMWPE)	Alternative for Fluoropolymers	Polyethylene is a material that can be extruded or film cast; however, this material does not impart any type of anti-adhesion (non-stick) properties, which make it unsuitable for a slick introduction into the human body.
Aryl Ketone polymer (PAEK)	Alternative for Fluoropolymers	PAEK mainly includes polyether ketone (PEK), polyether ether ketone ketone (PEEKK), polyether ketone ether ketone ketone (PEKEKK), polyether ketone ketone (PEKK), and polyether ether ketone (PEEK). PAEK It can be processed using all the typical thermoplastic processes, such as injection molding, extrusion, compression molding, additive manufacturing, and transfer molding. (Salamone, 1996) While PAEK is already being used for dental implants and other Medical Devices, it is a material that is very difficult to deposit into a device to give some of the desired properties of Fluoropolymers such as anti-adherence. ***Reference:*** Salamone, Joseph C. (1996), Salamone, Joseph C. (ed.), Polymeric materials encyclopedia, vol. 4, CRC Press, ISBN 978-0-8493-2470-3.
polyether block amide (Pebax 7233)	Alternative for Fluoropolymers	PEBAX is a material that is widely used in the MD industry, it can be extruded or film cast; however, this material does not impart any type of anti-adhesion (non-stick) properties, which make it unsuitable for a slick introduction into the human body.
Polyurethane (PU)	Intravenous cannulae	Intravenous Cannulas are already being made of PU and are a suitable replacement for the PTFE Cannulas that are in the market; however, the ease of use and insertion to the patient's body should be evaluated separately as a quality-of-life matter.
Rho-Coat™	Guidewires	ITGR made several attempts to contact Freudenberg Medical (FM) to obtain more information on Rho-Coat; there was no response from the company. Based on what the website for the product contains, this material can only be applied by a proprietary technique by FM and it is not a material or application technique they are willing to share with the public. FM states that this coating technique is used for their hypotubes; however, ITGR coats other types of metal substrates such as wires, mandrels, braided wire, guidewires, etc.
Polypropylene (PP)	Hernia Mesh	PP is already being used for Hernia Meshes as a single material or in combination with other materials (absorbable and non-absorbable); however, the selection of different materials is related to the properties the physician is looking for as well as the area of the hernia in the body. "For example, materials such as ePTFE have a good profile for adhesion risk but a high risk of infection. In contrast, Polypropylene meshes are durable and have a low infection risk, but they have little flexibility and a high adhesion risk." (Brown and Finch, 2010) ***Reference:*** Brown, C N, and J G Finch. "Which Mesh for Hernia Repair?" Annals of the Royal College of Surgeons of England, U.S. National Library of Medicine, May 2010, www.ncbi.nlm.nih.gov/pmc/articles/PMC3025220/.
Polyethylene terephthalate (PET)	Hernia Mesh	PET is already used for Hernia Meshes; however, the selection of different materials is related to the properties the physician is looking for as well as the area of the hernia in the body. PET as a material and as a composite have been extensively studied; please refer to ECRI reference below to deep dive uses and contraindications. ***Reference:*** Medical Device Material Performance Study Polyethylene Terephthalate ..., ECRI, 24 Nov. 2020, www.fda.gov/media/155399/download.

Polyethylene	Epidural catheters	Polyethylene is a material that can be extruded or film cast; however, this material does not impart any type of anti-adhesion (non-stick) properties, this material is already being used for epidural catheters and the ease of use and insertion to the patient's body should be evaluated separately as a quality-of-life matter for the patient.
Polyamides	Epidural catheters	Polyamides like Nylon are already being used for epidural catheters and the ease of use and insertion to the patient's body should be evaluated separately as a quality-of-life matter for the patient.
Liquid Cristal Polymer (LCP)	Implants	There was not enough data to comment on this topic.
Parylene C	Implants	Parylene C is a suitable option for coating implants and other substrates where you want some of the low coefficient of friction properties that Fluoropolymers provide; however, the Chemical Vapor Deposition Process that is used to apply this material is outside of ITGRs areas of expertise and would imply additional investment. Furthermore, to Process Parylene C and prevent surface defects, it is recommended to also use Silene as part of the process, this material is highly flammable and explosive.
Polyether ether ketone (PEEK)	Implants	PEEK is a very stable polymer with interesting properties; however, it is very rigid and difficult to extrude; it is not a good alternative to spray coat or dip which would entail melting the material and depositing it in a substrate.
Poly(methacrylic acid methyl ester)	Implants	PMMA is commonly used as bone cement and other type of implant cement/adhesive; it also has uses as the base of a co-polymer material for the intraocular lens market. The uses for this material are considered niche.
Polyimide	Implants	Polyimides are generally categorized as either thermosetting or thermoplastic. Thermosetting polyimide is widely used for coatings and film substrates; in this form it imparts excellent electrical properties and good thermal properties; however anti-adherence (low coefficient of friction) is not achieved with this material. Polyimide tubing is resistant to bursting, making it an excellent choice for endovascular/laparoscopy procedures.
SU-8	Implants	SU-8 is an epoxy-based negative-tone photoresist consisting of EPON SU-8 resin, solvent and a photoacid generator. As a versatile polymeric material, SU-8 has been extensively utilized to fabricate innovative MEMS devices, including many unique devices in the biomedical applications. Although the surface biocompatibility of SU-8 might not be completely biocompatible and suffers from toxic leachates, it seems that existing surface modification techniques, such as O2 plasma treatment or grafting of biocompatible polymers, might be sufficient to minimize biofouling. ***Reference:*** Chen, Ziyu, and Jeong-Bong Lee. "Biocompatibility of SU-8 and Its Biomedical Device Applications." *Micromachines*, U.S. National Library of Medicine, 4 July 2021, www.ncbi.nlm.nih.gov/pmc/articles/PMC8304786/.
Polydimethylsiloxane (PDMS)	Pacemakers, implants, synthetic blood vessels	While PDMS shows interesting properties such as hydrophobicity and excellent biocompatibility, ITGR was unable to find an economic and scalable manufacturing technique/process that would allow PDMS to be coated into a metal substrate for its use in hypotubes, wires, guidewires, mandrel, among others.