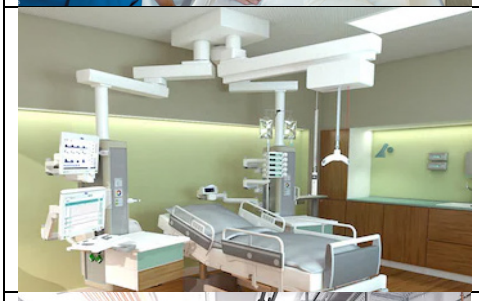
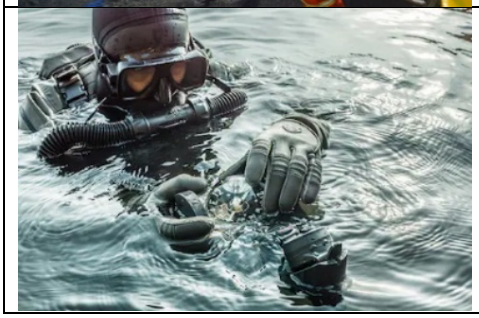
1. Products depending on Fluoropolymers

Dräger is a leading manufacturer of medical and safety technology. We do not use any chemicals that are harmful to health and belong to the PFAS group of substances, either in our products or in production. However, almost all of our products rely on components made of fluoropolymer materials such as PTFE, FKM, PVDF, PFPE or PCTFE to perform their function safely and durably.

Medical Technology		
	Ventilators	- Membranes, electrodes and electrolytes in electrochemical sensors - Oxygen-carrying components such as hoses, connectors, seals and lubricants - Breathing gas filters
	Anesthesia machines	- Membranes, electrodes and electrolytes in electrochemical sensors - Anesthetic and oxygen-carrying components such as hoses, connectors, seals and lubricants
	Incubators	- Membranes, electrodes and electrolytes in electrochemical sensors - Oxygen-carrying components such as hoses, connectors, seals and lubricants
	Patient Monitoring Systems	- Membranes, electrodes and electrolytes in electrochemical sensors
	Medical care systems	- Oxygen-carrying components such as hoses, connectors, seals and lubricants
	Hospital Gas Management Systems	- Oxygen-carrying components such as hoses, connectors, seals and lubricants

Safety Technology		
	Mobile Gas Detectors	- Membranes, electrodes and electrolytes in electrochemical sensors - Oxygen-carrying components such as hoses, connectors, seals and lubricants
	Stationary gas measuring systems	- Membranes, electrodes and electrolytes in electrochemical sensors - Oxygen-carrying components such as hoses, connectors, seals and lubricants
	Breathing apparatus for fire department	- High-pressure components such as hoses, connectors, seals and lubricants - Textile protective covers
	Circuit breathing apparatus for rescue forces	- Oxygen-carrying components such as hoses, connectors, seals and lubricants
	Diving rebreather for special forces	- Oxygen-carrying components such as hoses, connectors, seals and lubricants

	Blower-filter units for ergonomic occupational health and safety	- Highly stressed components exposed to pollutants
	Fire helmets	- Heat resistant visor
	Protective clothing such as chemical protective suits	- Chemical resistant and dirt repellent coating
	Oxygen self-rescuer for mining and industry	- Oxygen-carrying components such as hoses, connectors, seals
	Breathalyzer for police	- Membranes, electrodes and electrolytes in electrochemical sensors

2. Reason for use of Fluoropolymers

- Hoses, seals and other gas-carrying parts in medical devices must be permanently resistant to highly concentrated oxygen and, for example, anesthetic gases. In addition, high demands are placed on biocompatibility, i.e. the materials must be chemically inert and must not release any substances that are harmful to health, such as plasticizers. Some components, such as filters, also require both hydrophobic and oleophobic surface properties.
- In electrochemical sensors, which are used both in medical devices and in industrial gas measuring instruments, fluoropolymers are used in strongly acidic electrolytes (e.g. concentrated sulfuric acid) as semi-permeable membranes and in the electrodes to control their wetting and prevent dissolution. Connection wires made of platinum are electrically insulated with a PTFE coating. In lead-free oxygen sensors, which were introduced due to the RoHS directive, the materials must also withstand free oxygen radicals that would penetrate all other plastics.
- In stationary and mobile gas measuring instruments, the gas paths must not only be resistant to a wide range of aggressive substances, but also completely chemically inert so as not to falsify the measurement results. Only fluoropolymers such as PTFE and FKM meet these requirements. They also protect the sensors from aggressive media, e.g. in the chemical industry.
- Breathing apparatus for firefighters, industry and defence are exposed to harsh environmental conditions in many respects. Heat, cold, extremely high pressures and pollutants require sealing materials and breathing gas-carrying parts that can withstand these conditions.
- Recirculating breathing apparatus and diving rebreathers also work with concentrated oxygen, which results in special requirements for the chemical resistance of the gas-carrying components.
- Special requirements are placed on chemical protective suits and textiles for the protection of firefighting equipment with regard to resistance to harmful substances, heat and mechanical stress. To protect the health of users, special hydrophobic and oleophobic properties are also necessary to allow cleaning of harmful substances.

In addition, all electronic components contained in our products rely on **semiconductor components**, the production of which is currently not possible without PFAS to the best of our knowledge. To safeguard the supply chains, we are trying to increasingly source such components from Europe. Producing semiconductors in Europe as well is a declared goal of the EU Commission. This goal would be thwarted by a comprehensive PFAS ban.

In our **production plants,** components made of fluoropolymers ensure durability, energy savings and safe operation. We anticipate that a broad PFAS ban would result in the unavailability of the necessary production equipment to manufacture our products, including their spare parts.

3. Alternative

According to information from the manufacturers of our materials, there are no alternative materials that have the required properties for most of our applications. We had numerous discussions to explore possible alternatives, but due to the chemical-physical laws it is unanimously considered practically impossible that equivalent substitute materials will ever be available.

Even if it were possible to develop materials that cover all the required properties, they would necessarily be just as 'persistent' as fluoropolymers, because 'persistence' can also be translated as 'resistant' or 'chemically inert'. And these are precisely the key material properties that make these

materials so indispensable in our products in order to enable permanently safe application. In general, both are also highly desirable properties from an ecological and health perspective, as the materials are durable and do not emit harmful substances.

In some products, we have identified individual components that are exposed to lower chemical-physical requirements and for which we see potential to develop comparable substitute materials. The material development will usually take many years and might be not successful. In the limited number of cases where substitutes can be developed successfully, it must be taken into account that for medical and safety technology products, extensive qualification steps and lengthy approval procedures must be completed following material development and design modification. The total duration of this process can take up to 15 years. Even in this case other components of the finished product will still contain fluoropolymers.

4. Impact of the proposed restriction

a. Social and environmental impact - Medical technology

The restriction would result in the inability to manufacture and market essential medical equipment. Since spare parts are not exempted in the restriction proposal, inventory equipment would also become unavailable after a short period of time

Ventilators: Patients who are dependent on life-sustaining intensive care would often not survive without ventilators. The exact number of deaths cannot be calculated by us on a sound basis, but with several million intensive care treatments per year in Europe, it is certainly likely to be in the millions.

Anesthesia machines: Most vital operations would no longer be possible without anesthesia machines. The number of additional deaths cannot be determined precisely but is also likely to be in the range of several million.

Incubators: Around 500,000 babies are born prematurely in Europe every year and are dependent on incubators to survive. A high proportion of these premature babies would probably die without these devices.

Patient monitoring systems: without permanent monitoring of the vital functions of critically ill patients, in addition to the cases mentioned above, many of them would die or be seriously harmed.

Medical supply systems: A ban on fluoropolymers would initially result in a shorter service life of the supply units. It should be noted, however, that substitute materials may be harmful to health, as they are not sufficiently resistant to concentrated oxygen, for example, and may release decomposition products into the ventilation air. Such products would probably not be approvable.

Hospital gas management systems: Less resistant materials would compromise the safety of the hospital gas supply and the less reliable systems would likely not receive approval.

b. Social and environmental impact - Safety technology

Gas detection equipment: Mobile gas detection equipment protects workers in hazardous work areas from substances that are harmful to their health. Without this protective equipment, workers in many industries would be at risk of serious health hazards. Stationary gas detection equipment is an elementary component of plant safety, for example in the chemical industry or the oil and gas industry. Without this equipment, industrial disasters would be impossible to prevent, with serious consequences for people and the environment. Explosions on oil platforms or accidents involving the

escape of toxic gases in industrial plants are striking examples. These accidents regularly result in deaths, injuries and serious environmental damage.

In the detection of leaks of climate-damaging gases such as methane or refrigerants, stationary gas detectors also contribute to environmental protection in the normal operation of industrial plants. This also prevents emissions of PFAS (F-gases). Plant safety is also a decisive factor in the intended transition to a hydrogen economy. The detectors that detect leaks and flames at an early stage and thus prevent explosions would also no longer be available as a result of the restriction.

Respiratory protection equipment: Rescue forces such as fire departments or mine rescue teams can only carry out their work with reliable respiratory protection. If this equipment were no longer available due to the restriction, safe firefighting and rescue of people from dangerous situations would no longer be possible.

If fluoropolymer components are replaced with less resistant materials, the safety of rescue workers is at stake. Less reliable protective devices would probably also not be approvable in most countries.

Other firefighting equipment: In addition to textiles, other firefighting equipment must also meet special heat resistance requirements, such as the visors of firefighting helmets. Without this equipment, safe firefighting would not be possible.

Chemical protective suits: Without PFAS coatings, this protective equipment would not be able to meet the requirements, particularly with regard to chemical resistance, and would therefore not be able to fulfill its purpose. A health hazard for employees in industry and rescue forces would be the consequence.

Military diving apparatus (rebreathers): Special forces could no longer fully perform their tasks without these devices, e.g., defusing underwater mines or freeing terror victims.

c. Economic impact

Around 80% of our sales depend on products containing fluoropolymers (about 2 billion euros). In the event of a ban, the existence of our company would be threatened immediately or after a transitional period. As the largest industrial employer in Schleswig-Holstein, the economic impact on this state would be significant. Globally, most of our 16200 employees would lose their jobs.

d. Impact in case of a time-limited exemption

A time-limited exemption for the above-mentioned applications would have the consequence that the products would no longer be available after the end of the transition period. A review and, if necessary, extension of the exemptions is not provided for in the restriction proposal. The previously listed effects would therefore occur in full with a time delay.

5. Risk and emissions

Emissions of PFAS into the environment are generally not to be expected from our products. Among experts, it is undisputed that fluoropolymer materials themselves have no negative effects on health and the environment. On the contrary, these materials are used in medical devices, because they are so harmless to health and do not release any harmful substances, such as plasticizers. The fluoropolymer materials such as PTFE, FKM, PVDF, PFPE, PCTFE meet the OECD criteria as 'polymers of low concern'. They do not, however, meet the criteria of REACH Article 68 and, in our opinion, do not qualify for restriction on the basis of this article. Dossier submitters did not provide evidence that the manufacturing or end-of-life treatment of fluoropolymers lead to an unacceptable risk to human health or the environment

According to information from the raw material manufacturers, the production of the fluoropolymer materials mentioned is possible without emissions of harmful PFAS into the environment. To ensure this, corresponding emission restrictions would be a more appropriate way than an undifferentiated ban of the extremely heterogeneous substance group 'PFAS'.

In the disposal of our products, there is also no need to fear any environmental pollution with PFAS compounds that are harmful to health. Most of our very durable products are subject to extended producer responsibility in accordance with the WEEE Directive and are sent for regulated recycling via approved take-back systems. According to our information, the recycling processes for WEEE ensure that fluoropolymers are completely decomposed to HF and mineralized in the flue gas cleaning process. Even in the event that individual products end up in residual waste, studies confirm that no short-chain PFASs are emitted under the conditions of European waste incineration plants (>850°C) . Even in the event of improper disposal in the open air, a PTFE sealing ring, for example, would behave in an environmentally neutral manner.

6. Concentration limits for PFAS residues

According to our information, it is not possible to measure impurities of other materials with PFAS in the range of 25 ppb with the available routine analytical methods. By setting limits in the restriction proposal below the available measurement methods, manufacturers are exposed to considerable legal uncertainty. The limit values should therefore be adapted to the measurement limits of the available analytical methods.

We further assume that the analytical equipment also usually contains components made of fluoropolymers. Accordingly, if these materials were banned, analysis of PFAS would no longer be possible and the restriction could not be implemented in the proposed form.

7. Necessary changes to avoid negative effects

The following minimum conditions must be met in order to continue producing and marketing the above products:

- An indefinite exemption for fluoropolymers in medical devices and safety technology products, including accessories and spare parts
- An exception for means of production for the manufacture of these products, including accessories and spare parts
- An exception for the manufacture of semiconductors and electronic components

However, we fear that even these exceptions will not be sufficient to ensure the availability of essential medical and safety technology products. The reason is that we only process very small quantities of the fluoropolymer materials and the production of necessary components could no longer be profitable for our suppliers. We are already seeing major raw material manufacturers such as 3M pulling out of the production of fluoropolymers.

Conclusion: Only a broad exemption of fluoropolymers for professional uses can avoid the considerable negative social, environmental, and economic impacts of the proposed restriction.