To: Mr Aurel Ciobanu Dordea
DG ENVIRONMENT
Director Circular Economy
and Green Growth

Revision of the REACH Regulation: Ensuring the medical technology industry can still service EU healthcare system

We, as some of the key representatives of medical devices companies in the EU, in particular in-vitro devices (IVDs) and medical devices (MD) for professional use, have hereto decided to jointly write to you, to **urgently request a meeting to propose a solution to avoid a detrimental impact on the EU healthcare.**

The revision of the REACH Regulation, one of the key challenges under the EU Chemicals Strategy for Sustainability (CSS), has brought forward a discussion over the essential use concept, with the aim to phase out of the most harmful substances by only allowing uses that are proven essential for society and when there are no safer alternatives.

An efficient and effective scheme under REACH, RoHS and CLP for medical devices shall consider the following key issues:

- Medical devices are regulated by EU sectoral regulations (MDR / IVDR), both already considering the risk of the most harmful substances for humans and the environment for the whole life cycle.
- MDs and IVDs are extremely complex systems with a direct impact on patients' health. The specificity of MD and IVDs is translated into extended timelines required to develop and validate product changes (up to 5 years) and new generation products (up to 12 years).
- **Time is needed.** In our sector it takes a minimum 3 to 5 years just to assess the suitability of alternatives in legacy products (testing, validation, recertification) and even longer for new generation products.
- Hazardous substances are often essential to the functioning of these technologies yet are usually used in very low quantities, even as low as only a few grams per year for the whole EU. Derogations for extended periods of time are essential to allow medical devices to be brought to the market.
- The pressure of the current system regarding hazardous substances, which cannot be aligned with the industrial reality of our sector, has already caused significant impacts on innovation and development of new technologies and it seems to be destined to get worse.

In line with the above-mentioned points, **we urge EU institutions, and the European Commission particularly at this stage of the revision, to ensure that for medical devices the following is implemented:**

1. **Restrictions and Authorisations only apply to new product designs and not to legacy products and spare parts.**
2. **For new product designs, sufficient time is granted for substitution taking into consideration the design cycle of medical technologies.**
3. **That evidence collected through the substitution process can be used to apply for derogations later down the line.**

We, on our side, commit to implementing processes that ensure that for the most harmful substances – when technically, economically, and from a perspective of human health feasible, a) safer alternatives will be used in new product designs, and b) emissions from legacy products will be adequately controlled and gradually reduced.

We sincerely hope our concerns will be taken into consideration to ensure the revised REACH regulation could achieve the stated goals while at the same time promoting innovation and accessibility of medical devices.

Sincerely,

SIEMENS Healthineers EMEA	**Philips** Global Regulations & Standards
GE Healthcare Imaging Hardware Excellence	**Boston Scientific** IC/PI Systems