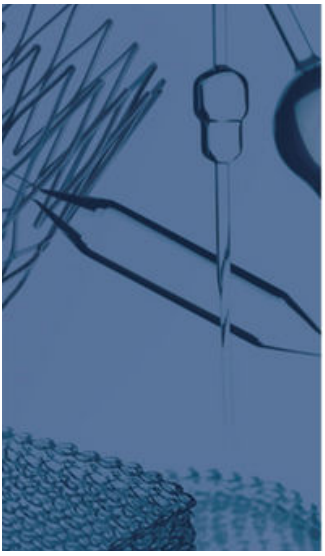

CONFLUENT

REACH and EU Medical Device Regulation (MDR) Compliance

Confluent Medical Technologies recently announced the ability to manufacture REACH and MDR Compliant Polyimide Tubing. This document explains what it means to be REACH and MDR compliant in the Medical Device industry and its importance in the contract manufacturing space.

What is REACH?

The EU REACH Regulation (Registration, Evaluation, and Authorization of Chemical Substances) requires industry to be responsible for the safe manufacture and use of chemical substances.

Who Does it Affect?

Both EU and Non-EU manufacturers and importers. Obligations exist for nearly all products, parts, substances, and mixtures manufactured in or imported into Europe.

European Union (EU) Medical Devices Regulation (MDR)

It establishes a regulatory framework for medical devices that safeguards public health and safety while supporting the competitiveness of the market. The Regulation (EU) 2017/745 aims to provide a consistent approach to ensure safe use and access for medical devices in the EU. The update to the Regulation (2017/745), under Chapter II of Annex I requires justification for use of substances potentially harmful to patients and end users. Materials with direct and indirect exposure to patients and end users may not contain > 0.1% w/w of carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B in addition to carcinogenic and toxic to reproduction, of category 2, in accordance with Part 3 of Annex VI from Regulation (EC) No 1272/2008 and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health

For further details and compliance-related customer requests please contact **Azam Ali at azam.ali@confluentmedical.com**

What is SVHCs?

A **Substance of Very High Concern** is a chemical substance proposed to be subject to authorization under the REACH regulation, which might lead to restrictions of use for the substance. Criteria to propose a chemical substance to be added to the SVHC list include that the substance is a CMR (Carcinogenic, Mutagenic and/or Reprotoxic) , ED (Endocrine Disruptors), and or PBT/vPvB (Persistent, bioaccumulative and toxic) substance. Notably, a SDS (safety data sheet) will include any SVHC that is contained in a mixture of substances at 0.1% w/w. Thus, the information if a SVHC is contained in a contact material is available in the SDS. The number of SVHCs requiring declaration is increasing every 6 months. **By January 2010, there were 30 SVHCs in the Candidate list and now as per the latest European Chemicals Agency (ECHA) list issued on June 14, 2023, there are 235 SVHCs in the list and it is continuously increasing.**

BEFORE:

European Chemical Agency (ECHA) Guidance Manufacturers were required to communicate if there are any SVHCs (substances of very high concern) above 0.1% w/w of the finished product.

NOW:

European Court of Justice (ECJ) Ruling The new ruling will require manufacturers to communicate if there are any SVHCs (substances of very high concern) above 0.1% w/w of a component/material within the product.

NEED TO UNDERSTAND our Suppliers PRODUCT COMPOSITION at a COMPONENT and MATERIAL LEVEL to identify communication requirements at all levels

Work with our Subject Matter Experts To:

1. **Review** product composition and identify high-risk components and materials for SVHCs.
2. **Collect** the necessary compliance documentation by working within the organization and with our suppliers
3. **Ensure** we have the proper communications in place for compliance where necessary and fulfill our valuable customer requirements.

For further details and compliance-related customer requests please contact **Azam Ali at azam.ali@confluentmedical.com**