



REACH Compliance Declaration

Background:

The European Union's REACH legislation entered into effect on 1st June 2007 to streamline and improve the former legislative framework for chemicals in the European Union (EU). REACH regulates substances (chemicals) including substances in preparations (mixtures) and substances in products (articles).

Under REACH, molded silicone components are considered to be "Articles" per ECHA (European Chemicals Agency) an article is "an object, which during production is given a special shape, surface, or design that determines its function to a greater degree than does its chemical composition." Per this definition [ProMed](#) is considered to be a producer of "Articles".

Producers of "Articles" need to be concerned about two (2) conditions:

- Substances contained in "Articles" when "they are intended to be released under normal or reasonably foreseeable conditions of use". For example – Aerosol spray can that contains paint. The substances contained in silicone components are usually not emitted under normal use and therefore will not have to be registered.
- "Articles" containing SVHCs (Substances of Very High Concern) must be registered if they contain any SVHC in concentrations greater than 0.1% of "Article" weight.

ProMed's Position on REACH and Related Compliancy:

[ProMed](#) does not have or manufacture its own products. [ProMed](#) manufactures molded silicone components per designs provided by its customers on contract basis. It is [ProMed's](#) position that its customers define and own their product design, Bill of Material (BOM), and it's associated Approved Manufacturer's List (AML). And to that end [ProMed](#) feels its customers have total ownership and responsibility for identifying and specifying the components on their BOM to meet compliance requirements by European Union or other regulatory agencies.



It is ProMed's policy to build customer products in full compliance with customer's design and Bill of Material. ProMed does not and will not deviate from Customer's Bill of Material unless it has full approval and consent from its customers.

During the course of manufacturing ProMed uses medical grade silicone and component cleaning agents that might fall under REACH compliancy requirements. Most of these process related materials and solvents are washed off assemblies before they are packaged and shipped to our customers. Therefore reporting of these substances are not required.

However there are some process related materials, substances, and solvents that remain on assemblies after they are shipped (materials such as adhesives used in component assemblies). ProMed systems will identify these materials and determine if they contain any SVHC. Material Composition and Declaration form IPC- 1752 will be completed and maintained in a database. Compliancy certifications then can be issued by assembly based on the 0.1% weight threshold requirement under REACH.

ProMed can provide referrals and contacts to companies that offer REACH related services.

Please direct your questions and inquires to your ProMed Sales or Customer Service Representative.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Parsons".

Robert Parsons
Vice President Quality Assurance & Regulatory Affairs

A handwritten signature in black ink, appearing to read "Peter Mangan".

Peter Mangan
President