



unimed

www.unimed.ch

INFORMATION SHEET

Avenue du Tir-Fédéral 56
1024 Ecublens
Switzerland
Tel: +41 21 624 21 51
info@unimed.ch

SUBJECT	Material Compliance Certificate (REACH, RoHS, PFAS, Conflicts minerals, ...)	CERTIFICATE #	CERTCONFMAT.FIE
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UNIMED hereby certifies that all products manufactured are free or within the accepted limits from any substances concerned by the following current rules, regulations, directives and acts.

- EU RoHS Directives.
- EU REACH substances of very high concern (SVHC) Regulation, except for the Cobalt (CAS # 7440-48-4) which can exceed 0.1 % w/w in the composition of stainless steel¹.
- EU Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) Regulation.
- EU Persistent Organic Pollutant (POP) Regulation.
- USA Conflict Mineral - Dodd-Frank Wall Street Reform and Consumer Protection Act.
- USA California Proposition 65 - Safe Drinking Water and Toxic Enforcement Act.
- USA Toxic Substances Control Act (TSCA).
- Canadian Environmental Protection Act (CEPA).
- PVC, Latex and Di-(2-ethylhexyl) phthalate (DEHP) Substance.
- Medicinal substance, Animal tissue and human blood-derived products.
- Per and polyfluoroalkyl (PAFSs) - i.e, contains fully fluorinated methyl (CF3) or methylene (CF2) carbon atom (without any H/Cl/Br/I attached to it).
- Bisphenol A (BPA) substance.
- Nitrosamine impurities or nitrosating agents.

UNIMED therefore declares that its products comply with the above regulations, directives and acts.

UNIMED SA

Claude Borgeaud
Quality Director

¹ *Stainless steel is considerate as a Cobalt-containing alloy (CoCA) that was not considerate during the Cobalt opinion given by the European Chemicals Agency (ECHA) Risk Assessment Committee (RAC). Justification of use of CoCA was provided by a group of medical device companies coordinated by MedTech Europe (see [report](#)).*

All this information is for reference only. They have no legal or contractual commitment Unimed SA.

16.03.2026	Page 1/1	
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