



MEDICAL DEVICE COMPONENTS

12205 World Trade
Dr. San Diego, CA
92128

Date: March 26, 2025

Subject: Declarations for components made at Medical Device Components, LLC

We have reviewed the initial EU REACH Regulation (EC) No.1907/2006 together with its amending regulations including EU REACH updates made to the date of this declaration. We are complying as follows:

1. It is our understanding that products categorized as articles are exempt from registration and notification requirements under the EU REACH regulation, provided they do not intentionally release substances during use and do not contain designated Substances of Very High Concern (SVHC) listed on the REACH Annex XV Candidate List for Authorization.

We have reviewed the EU REACH SVHC regulations and updates as of January 21, 2025, which now include a total of 247 substances of Very High Concern on the Candidate List, the articles manufactured by Medical Device Components, LLC meet these exemption criteria.

2. We have reviewed Annex VI to CLP ATP 18. Nickel/platinum wire contains nickel. Platinum/Cobalt wire contains cobalt. All other Medical Device Components, LLC components from US/Mexico based operations do not contain chemicals listed in the Annex VI to CLP ATP 18 list.

We have reviewed CLP Regulation (EC) 1278/2008 – ATP 18 (Category 1A, 1B CMRs, and Eds (Carcinogen 2, and Toxic to Reproduction 2)). Medical Device Components, LLC components from US/Mexico based operations do not contain chemicals listed in the Carcinogen 2 and Toxic to Reproduction 2 legislation.

We have reviewed BPR Regulation (EU) 528/2012 – BPR list for Eds (Human Health) as published 23 January 2023. Medical Device Components, LLC components from US/Mexico based operations do not contain chemicals listed in the Human Health legislation.

We have reviewed 2011/65/EU (RoHS 2) and Directive (EU) 2015/863 (RoHS 3). Medical Device Components, LLC components from US/Mexico based operations do not contain chemicals listed in the RoHS 2 and RoHS 3 legislation.

We have reviewed the state of California Proposition 65 Safe Drinking Water and Toxic Enforcement Act of 1986. Nickel/Platinum wire contains nickel. Platinum/Cobalt wire contains cobalt. All other Medical Device Components, LLC components from US/Mexico do not contain chemicals listed in the Prop 65 legislation.

We have reviewed the EU MDR (Medical Device Regulation EU 2017/745). Medical Device Components, LLC components from US/Mexico based operations do not contain chemicals more than the thresholds listed in EU MDR legislation.

We have reviewed the EPA Persistent, Bio accumulative, and Toxic (PBT) Chemicals under TSCA Section 6(h) regulation. Medical Device Components, LLC components from US/Mexico based operations do not contain chemicals more than the thresholds listed in TSCA section 6(h) legislation.

We have reviewed the Eco-design Directive (2009/125/EC). UV-328 is not currently added to the EU Persistent Organic Pollutants resolution. If approved the new law will apply from February 26, 2025.

Medical Device Components, LLC components from the US/Mexico based operations ensures packaging complies with EU Packing Directive 94/62/EC.

We will be glad to provide our customers with support in relation to any specific questions they may have regarding our products to assist their exporting efforts.

Sincerely,



Scott Rose, COO
Medical Device Components, LLC