MEDICAL DEVICE COMPONENTS
12205 World Trade Dr.San Diego, CA 92128

June 1th, 2026

Subject: Declarations for Components Sold by 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 as of 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.

2. We have reviewed the EU REACH SVHC regulations and updates as of February 4th, 2026, which now include a total of 253 substances of Very High Concern on the Candidate List and the articles manufactured by Medical Device Components, LLC meet these exemption criteria.

3. 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.

4. 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. As such, Medical Device Components LLC complies with TSCA, the Toxic Controls Substances Act (TSCA) and meets the compliance requirement for endocrine-disrupting substances (ED) are non-existent and meets the threshold for such Eds to be under 0.1% weight by weight concentration (w/w).

5. 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.

6. 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.

7. We have reviewed the state of California Proposition 65 Safe Drinking Water and Toxic Enforcement Act of 1986. Nickel/Platinum wire contains nickel.

8. 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.

9. 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. Medical Device Components further declares that products manufactured and supplied by us do not contain natural rubber latex, nor do they come into contact with natural rubber latex at any stage of the manufacturing, assembly, packaging, or handling processes, as applicable.

10. 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. As such, Medical Device Components LLC complies with TSCA, the Toxic Controls Substances Act (TSCA), 1976.

11. 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.

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

13. Medical Device Components LLC declares that none of our products are of human origin or animal origin, nor do they contain any non-viable biological derivatives. All materials used in our products are derived from non-biological sources and are manufactured through controlled, non-biological processes in compliance with applicable regulatory and quality standards.

14. Medical Device Components LLC declares that, as of the effective date of this clause, all products manufactured, imported, or distributed within the European Economic Area fully conform to the provisions **of Regulation (EC) No 1272/2008**, and no product is placed on the market without appropriate hazard classification, labelling, packaging, and notification as required by law.

15. Medical Device Components LLC declares that, as of the effective date of this clause, most precious metal products manufactured, imported or distributed do not contain any PVC (polyvinyl chloride), PFAS (polyfluoroalkyl), phthalates,

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Bisphenl A or BPA Derived Plastics, colorants or nickel compounds, with the exception of our Nitinol products which contain 50% Nickel.

Should you have questions related to this declaration regarding these compliance declarations, please reach out to us at esg@medicaldevicecomponents.com.

Sincerely,

Scott Rose
Chief Operating Officer
Medical Device Components LLC