



September 24th, 2025

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. We have reviewed Annex XVII of REACH Regulation (EC) No. 1907/2006 and confirm that Medical Device Components LLC components from US/Mexico based operations do not contain substances restricted under Annex XVII above applicable thresholds.
2. We have reviewed the EU REACH SVHC regulations and updates as of June 5th, 2025, which now include a total of 250 substances of Very High Concern on the Candidate List and the articles manufactured by Medical Device Components, LLC meet these exemption criteria.
3. As none of Medical Device Components LLC articles contain substances of very high concern (SVHC) above 0.1% weight by weight, there are no notification requirements under the Waste Framework Directive (2008/98/EC) SCIP database.
4. 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.
5. 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.
6. 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.



7. 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.
8. We have reviewed the state of California Proposition 65 Safe Drinking Water and Toxic Enforcement Act of 1986. Nickel/Platinum wire contains nickel.
9. 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.
10. 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.
11. 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.
12. We have reviewed the Ecodesign for Sustainable Products Regulation (ESPR) adopted in May of 2024 and can confirm that Medical Device Components LLC meets these requirements.
13. UV-328 was added to the EU's Persistent Organic Pollutants (POPS) Regulation published on July 15, 2025, and entering into force on August 4, 2025. Medical Device Components LLC confirms that our products do not contain UV-328 above the specified thresholds.
14. Medical Device Components LLC components from the US/Mexico based operations ensures packaging complies with EU Packing Directive 94/62/EC.

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

Sincerely,

A handwritten signature in blue ink, appearing to read 'Scott Rose'.

Scott Rose
Chief Operating Officer
Medical Device Components LLC