



MEDICAL DEVICE COMPONENTS

12205 World Trade Dr.
San Diego, CA 92128

Date: 7/16/24

Re: 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/ notification duties provided they do not intentionally release substances during use, and they do not contain designated Substances of Very High Concern (SVHC) on the REACH Annex XV Candidate List for Authorization. The articles that Medical Device Components, LLC manufacturers meet these exemptions.
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 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 more than the thresholds 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 based operations 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, Bioaccumulative, 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 EU Persistent Organic Pollutants (POPs) regulation. Medical Device Components, LLC components from US/Mexico based operations do not contain chemicals more than the thresholds listed in EU POPs legislation.

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.

Scott Rose, COO
Medical Device Components LLC