

MANUFACTURER STATEMENT

EU MDR 2017/745 DECLARATION

PHthalATES, SUBSTANCES CARCINOGENIC, MUTAGENIC OR TOXIC TO REPRODUCTION

The ADMEDES Group (hereinafter referred to as ADMEDES) hereby confirms that the components / parts of medical devices produced for our customers do not incorporate as integral parts phthalates and substances which are carcinogenic, mutagenic, or toxic to reproduction at levels above 0,1%w/w. This is in accordance to the hazardous substance lists referenced in the EU MDR – REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND COUNCIL OF 5 APRIL 2017 Section 10.4.1:

- EU Classification, Labelling and Packaging (EC) No 1272/2008 for substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, Annex VI to CLP ATP17 in force **17 December 2022**.
- EU REACH (EC) No 1907/2006 for substances having endocrine-disrupting properties, published in accordance with Article 59 (10) of the REACH Regulation updated **19 January 2022**.
- The Biocidal Products Regulation (BPR), Regulation (EU) 528/2012 for substances having endocrine-disrupting (ED) properties for human health, in print as of **20 January 2022**.

For and on behalf of ADMEDES

Signed in Pforzheim

Date: 11-04-2022



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