

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 December 17 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 January 19 2022.

For and on behalf of ADMEDES

Signed in Pforzheim

Date: 03-24-2022



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