

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 and parts of medical devices manufactured for our customers do not contain, as an intentional component or integral part, any phthalates or substances classified as carcinogenic, mutagenic, or toxic to reproduction (CMR category 1A or 1B), nor substances with endocrine-disrupting properties, at levels above 0.1% w/w.

This declaration is made in accordance with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (EU MDR), Annex I, Chapter II, Section 10.4.1, and refers to the following substance classifications:

- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP) – Annex VI, as amended by:
 - ATP 17 (in force since 17 December 2022),
 - ATP 18 (in force since 23 November 2023),
 - ATP 21 (applicable from 1 September 2025),
 - and ATP 22 (applicable from 1 May 2026);
- Regulation (EC) No 1907/2006 (REACH) – Candidate list of substances of very high concern (SVHC) published in accordance with Article 59(10), as last updated on 21 January 2025;
- Regulation (EU) No 528/2012 on biocidal products (BPR) – for substances identified as endocrine disruptors for human health, as published on 23 January 2023.

This declaration reflects the current regulatory status as of the date below.

Signed in Pforzheim

Date: 25 April 2025

For and on behalf of ADMEDES

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This information is believed to be accurate and refers to the laws, regulations and products at the date of issue. However, ADMEDES makes no express or implied representations or warranties with respect to the information contained herein. It is the responsibility of our customers to determine that their products are safe, lawful, and technically suitable for their applications. Because of possible changes in the laws and regulations, we cannot guarantee that the status of this article will remain unchanged.