EFINEA

Capabilities Beyond Infinity

January 1, 2024

The Regulation (EU) 2017/745 aims to ensure a consistent approach to ensure safe use and access for medical devices in the European Economic Area (EEA). The update to the Regulation (2017/745), under Chapter II of Annex I requires justification for use of substances potentially harmful to patients and end users. Materials with direct and indirect exposure to patients and end users may not contain 0.1% w/w of carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B in accordance with Part 3 of Annex VI from Regulation (EC) No 1272/2008 and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health.

EFINEA certifies that it is compliant with the requirements of The Regulation (EU) 2017/745.

This Declaration is based upon information provided to us by our suppliers of raw materials and/or components used in the manufacture of EFINEA's products.

Should you have any further questions, do not hesitate to contact us.

Sincerely,

Ann Zanders

Ann Zanders – Director of Quality Assurance

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