XL Precision Technologies

28th February 2024

Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

Statement of XL Precision Technologies Compliance with the Medical Device Regulation

The Regulation (EU) 2023/607 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 (2023/607), 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.

This communication applies to all products sold or otherwise placed on the market by XL Precision Technologies prior to the signature date of this declaration, and certifies that none of our products contain substances above threshold currently restricted under EU MDR.

Graeme Lea

Head Of Quality

Tom Graham

Managing Director

Company No. 3686730
VAT No. 733912632
www.xlprecisiontechnologies.com

info@xl-pt.com

XL Precision Technologies Ltd
79 Teesside Ind Est
Stockton on Tees
UK
TS17 9JY
Tel: (44) 1642 766960