XL Precision Technologies

Date: 4th March 2019

Medical Devices Regulation (MDR (EU) 2017/745)

XL Precision Technologies Ltd (XL-PT) is a contract manufacturer of components and sub-assemblies used primarily in medical devices. Design specification is owned by our customers and XL-PT does not hold any technical files for the completed device.

The new Medical Device Regulations (MDR) comes fully into force in May 2020 and places extra responsibilities on the device manufacturer, importer and distributor. There are no additional requirements on companies who are supplying components to the "device manufacturer".

XL-PT is continuing to review the MDR guidelines, related to authorised body requirements and how that translates through the supply chain. There is no anticipated effect.

The current interpretation is that approval to ISO13485:2016 will continue to be the relevant qualification and standard for contract manufacturing of medical devices.

Tom Graham
Managing Director

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