EU MDR statement

The European Medical Device Regulation (Regulation (EU) 2017/745, MDR) came into force on 25 May 2017 with a transition period which ended on the 25 May 2021. It replaces both the Medical Devices Directive 93/42/EEC (MDD) and the Directive relating to Active Implantable Medical Devices 90/385/EEC (AIMDD).

Section 10.4.1 of the EU MDR states that devices or their materials which have invasive contact with the human body or administer/store fluids or gases which contact the human body must contain a concentration below 0.1 % weight by weight of the following substances unless justified with reference to Section 10.4.2.

Substance Name	Restriction Threshold
Substances that are carcinogenic, mutagenic, or toxic to reproduction ("CMR substances") of category 1A or 1B	0.1 %
Substances with endocrine-disrupting properties ("ED substances")	0.1 %

XP Power has reviewed Section 10.4.1 of the EU MDR addressing CMR and ED substances requirements. XP Power products are assembled as components into final products by medical customers and they are considered as components without medical function. Therefore, our medical-based products are not classified as medical devices. Our medical-based products also do not contain part which has invasive contact with the human body, or any material which transports or stores fluids or gases which contact the human body. Hence, CMR and ED substances requirements are not applicable to our medical-based products.

We understand the challenges our medical customers are facing and the need to identify the materials contained in their products. Even though XP Power products are not in scope of substance reporting as medical devices, XP Power has established internal Material Compliance program by which we conduct on-going survey to material suppliers and support customers with the information of CMR and ED substances content upon request in order to help customers fulfil their EU MDR obligations.

Signed:

Gavin Griggs
Chief Executive Officer

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