May 26, 2021

EU MDR Update

Dear Valued Maxtec Customer,

EC REPRESENTATIVE CHANGE

In preparation for Medical Device Regulation (EU) 2017/745, commonly referred to as MDR, Maxtec, LLC is transitioning our EC Representative from QNET to Emergo.

On market references and manufactured inventory may contain reference to our outgoing EC representative, QNET, as we make this transition.

MAXTEC CLASS I MEDICAL DEVICES

Class I, non-measuring, non-sterile, medical devices have been transitioned to MDR. Maxtec's Class I, non-measuring, non-sterile medical devices' Declaration of Conformity have been updated and include Maxtec's SRN number and their corresponding Basic UDI DI.

MAXTEC CLASS IIA AND HIGHER MEDICAL DEVICE

Maxtec Class IIa devices and higher are maintained under the Medical Device Directive 93/42/EEC until May 26, 2024. Maxtec's EC Certificate number is G1 045041 0025 Rev 00.

To review Maxtec's updated Declarations of Conformity please visit www.maxtec.com

www.maxtec.com
PHONE: 385.549.8000 · TOLL FREE: 866.4.Maxtec · FAX: 801.973.6090
2305 South 1070 West · Salt Lake City, UT · 84119 · USA