SÖHNGEN®
First Aid • Emergency Medical Systems

Confirmation of compliance with Regulation (EU) 2017/745

02-2021

Dear Business Partner,
Regulation (EU) 2017/745 (Medical Device Regulation - MDR) of the European Parliament and of the Council dated 05 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC (AIMDD) and 93/42/EEC (MDD), has entered into force on 25 May 2017. It was last amended by Regulation (EU) 2020/561 of 23 April 2020. With effect from 26 May 2021, the application of the MDR is mandatory. The previous Directives mentioned above are repealed and replaced by the MDR. However, Article 120 (3) MDR provides that a device, which is a Class I device according to Directive 93/42/EEC, for which a Declaration of Conformity was drawn up before the date of application and for which the conformity assessment procedure according to the MDR requires the involvement of a Notified Body or for which a valid Certificate according to Directive 93/42/EEC exists, may continue to be placed on the market until 26 May 2024, provided that it continues to comply with one of these Directives and the additional requirements under the MDR as of the effective date.

Having said this, we confirm with effect from 26.05.2021 for the following medical devices manufactured by us

CONFIRMATION

Class I medical devices

- The products meet the requirements of the MDR
- Within the framework of the conformity assessment procedure to be applied according to MDR, an EU Declaration of Conformity has been drawn up
- The products bear the CE marking
- The devices are accompanied by the safe use information
- The devices have been assigned a basic UDI-DI Class

Class Is medical devices

- A valid MDD Certificate from our Notified Body, BSI NL (2797), valid until 26.05.2024, is available for these products
- Within the framework of the conformity assessment procedure to be applied according to the MDD, an EU Declaration of Conformity was drawn up before the MDR came into force
- The products bear the CE marking and the identification number of our Notified Body, 2797 = BSI NL
- The products are accompanied by the safe use information
- The devices continue to comply with the requirements of the MDD
- The requirements of the MDR with regard to post-market surveillance, market surveillance, vigilance and registration of economic operators and products are fulfilled

Taunusstein, 17.02.2021

René Ay
Quality Management Representative

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