**medi GmbH & Co. KG**
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April 28th 2021

**Confirmation for medi partners**
**regarding compliance with the requirements according to Article 14**
**(EU) 2017/745 (MDR)**

Dear medi Partner,

We confirm that the medical devices supplied by us in the role of manufacturer according to Article 10 MDR or the medical devices for which we are distributor according to Article 14 MDR complies with Regulation (EU) 2017/745 (MDR):
a) All medical devices are CE marked and an EU certificate of conformity has been drawn up.
b) The device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11).
c) For imported devices, the importer has complied with the requirements set out in Article 13(3).
d) A UDI was assigned by the manufacturer.

For medical devices for which the transitional period under Article 120 MDR is still applicable until May 26th 2024, the legal basis is conformity with Directive 93/42/EEC. However, the requirements of the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices also apply to them.

As a part of our certified quality management system for medical device manufacturers according to ISO 13485:2016, we demonstrate compliance with the general safety and performance requirements by means of a conformity assessment procedure according to Annex IV of Regulation (EU) 2017/745 and document this by means of the EU declaration of conformity and the CE mark



**Commercial Registry Bayreuth** HRA 529/HRB 166
**USt-ID Nr.** DE 132354257
**Personally liable partner** medi Verwaltungsgesellschaft mbH
**Management** Stefan Weihermüller · Gerhard Kolb · Dirk Treiber
**AEOF Nr.** DE AEOF 100167

**HypoVereinsbank**
**IBAN** DE26 7732 0072 0003 0241 48
**BIC** HYVEDEMM412

**VR Bank Bayreuth-Hof**
**IBAN** DE42 7806 0896 0006 2059 76
**BIC** GENODEF1HO1

on the medical devices. It is therefore not necessary to pass on the individual CE declarations to our medi partners.

For the corresponding storage and transport conditions, please refer to the respective labelling on the products supplied, whereby the following primarily applies here for medi products (medi GmbH & Co. KG next to the manufacturer symbol = manufacturer according to Article 10 MDR):
Store in a dry place and protect from the direct sunlight.

**Please inform us in the following cases:**
If you consider or have reason to believe that a device supplied by medi is not in conformity with the requirements of the MDR, do not make the device available on the market and inform the manufacturer indicated next to the factory symbol.

To minimize risks to users and patients, immediately forward complaints and reports from healthcare professionals, patients or users about suspected incidents related a medi product. Please also keep us informed about complaints, about non-conforming devices and about recalls and withdrawals so that we can continuously improve our products.
Thank you very much for your support!

Do you have any questions? Our customer centre, via hotline 0921 912-111, and the medi QM team, via e-mail to Grp.QM@medi.de, are happy to help.
Current certificates and further information on our products can be found on our medi website:
www.medi.de/en/products/quality-standards/

Kind regards

Oliver Gramalla
Quality Management Supervisor medi