

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III Certificate No. MDR-002

Issued to: KIRCHNER & WILHELM GmbH + Co.KG

Eberhardstrasse 56, 71679 Asperg

Germany

SRN of the manufacturer: DE-MF-000006338

EU authorised representative: Not applicable

SRN of EU authorised

representative: Not applicable

SIQ has audited the quality management system – restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements – in accordance with MDR Annex IX and found that the above-mentioned Manufacturer's quality management system meets the requirements of the Regulation (EU) 2017/745 concerning medical devices Annex IX. Devices covered by the Manufacturer's quality management system are listed on the page(s) below.

This certificate is based on

Audit report No.:

OSV 00652/2023, 2023-05-31,

OSV 00565/2023, 2023-05-30,

OSV 01178/2023, 2023-09-27.

See also decision of NB's commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality management system is subject to periodical surveillance as referred to in Regulation (EU) 2017/745 concerning medical devices Annex IX and continues to meet the above requirements.

Reference to any previous certificate: /

Certification date: 2023-09-27

Issue: 01/2023-09-27

Valid until: 2028-09-26

Managing Director of SIQ-

regor Schos

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EU Quality Management System Certificate Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III Certificate No. MDR-002

Device: Aneroid sphygmomanometers

EMDN: C9006

Intended purpose: /

Classification: I measuring function

Specific conditions for or / provisions or limitations to the validity of certificate: