



EC Certificate – Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V
Certificate No. MDD-128

Issued to: Kirchner & Wilhelm GmbH + Co. KG
Eberhardstrasse 56, 71679 ASPERG, Germany
Product category: Blood pressure measuring devices
UMDNS: 16-156

SIQ has audited the quality system in accordance with MDD Annex V, restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex V, including all subsequent amendments. This certificate is based on:

Audit report No.:

OSV 00357B/2019, 2019-04-11

OSV 00022/2019, 2019-02-25

OSV 01182/2018, 2018-10-29

OSV 00984/2018, 2018-08-30

OSV 00921/2018, 2018-08-20

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

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex V (4), restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements and continues to meet the above requirements.

Certification date: 2019-04-04

Issue: 2/2019-04-12

Valid until: 2024-04-04



Director of SIQ

Igor Likar