

EC Certificate – Production Quality Assurance Directive 93/42/EEC on Medical Devices, Annex V Certificate No. MDD-122

Issued to: KIRCHNER & WILHELM GmbH + Co.KG

Eberhardstrasse 56,

71679 ASPERG, Deutschland

Place of production: KIRCHNER & WILHELM GmbH + Co.KG

Eberhardstrasse 56,

71679 ASPERG. Deutschland

Product category: Iontophoresis units

GMDN: 12-185

SIQ has audited the quality system in accordance with MDD Annex V and found that the abovementioned 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 00798/2018, 2018-07-30 OSV 00921/2018, 2018-08-20 OSV 01173/2018, 2018-11-28 OSV 01182/2018, 2018-10-29 OSV 01433/2018, 2019-01-10

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) and continues to meet the above requirements.

Certification date: 2019-01-10

Issue: 1/2019-01-10

Valid until: 2024-01-10

SIQ Liubijana d Tržažka cesta 2 SI-1000 Ljubijana / Slevenja Director of SIQ

Igor Likar