



EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-169

Issued to: SHP Steriltechnik AG
Detzel Schloss 1, D-39345 Satuelle
Germany

Place of production: SHP Steriltechnik AG
Detzel Schloss 1, D-39345 Satuelle
Germany

Product category: Steam Sterilizers

GMDN: 40547,
38671

SIQ has audited the quality system in accordance with MDD Annex II excluding (4) and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex II. This certificate is based on

Audit report No.:

OSV 00974/2019, 2019-09-09
OSV 01564/2019, 2020-02-28
OSV 00362/2020, 2020-04-21
OSV 00278/2020, 2020-05-18
OSV 00396/2020, 2020-05-29

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 II (5) and continues to meet the above requirements.

Certification date: 2020-06-19

Issue : 1/2020-06-19

Valid until: 2024-05-27



Director of SIQ

Igor Likar