



EC Certificate – Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V
Certificate No. MDD-077

Issued to: Safersonic Medizinprodukte Handels GmbH
Hauptstraße 16/2, 3680 Persenbeug-Gottsdorf, Austria

Product category: Sterile Wrappers for Ultrasonic Probes
GMDNS/UMDNS: 14464

Product category: Sterile kits: Wrappers for Ultrasonic Probes with Ultrasonic
Transmission Gel
GMDNS/UMDNS: /

Product category: Sterile Ultrasonic Gel
GMDN/UMDNS: 58735

SIQ has audited the quality system in accordance with MDD Annex V 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 00662/2021, 2021-05-25

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: 2017-05-31
Issue: 07/2021-05-25
Valid until: 2024-05-26



Director of SIQ
Gregor Schoss

