EC Certificate – Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate No. MDD-199

Issued to:	Eonex medical GmbH Schubertstraße4, 78604 Rietheim-Weilheim, Germany
Place of production:	Eonex d.o.o. Gospodarska ulica 6, Slobodna zona Varaždin 42 202 Trnovec Bartolovečki, Croatia
Product category:	Internal orthopaedic fixation system, nonbioabsorbable, nonsterile
UMDNS/GMDN:	Plates, Bone – 13-050/ 61573 Screws, Bone – 16-10 / 56642

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 00202/2021, z dne 2021-03-08
OSV 00657/2021, z dne 2021-05-25
OSV 00676/2021, z dne 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 II (5) and continues to meet the above requirements.

Certification date: 2021-05-25

Issue: 1/2021-05-25

Valid until: 2024-05-26

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Managing Director of SIQ

Gregor Schoss