



EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-165

Issued to: ORTOKON DOO NIŠ
Bulevar svetog cara Konstantina 80-86, 18000 Niš
Serbia
Place of production: ORTOKON DOO NIŠ
Bulevar svetog cara Konstantina 80-86, 18000 Niš
Serbia
Product category Nonactive orthopaedic implants: External Bone Fixation system
Mitković
GMDN: 35647

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 00566/2018, 2018-06-08
OSV 01244/2018, 2018-11-30
OSV 01463/2018, 2019-03-15
OSV 00197/2019, 2019-05-16
OSV 01084/2019, 2019-11-29
OSV 01551/2019, 2020-04-30

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: 2020-05-14

Issue : 1/2020-05-14

Valid until: 2024-05-27



Director of SIQ

Igor Likar