



EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-132

Issued to: NARCISSUS d.o.o.
Vuka Karadžića 24, 24430 Ada, Serbia

Place of production: NARCISSUS d.o.o.
Molski Put 3, 24430 Ada, Serbia

Product category: DHS systems
GMDN: 34003

Product category: Partial hip replacement
GMDN: 33704, 55834

Product category: Intramedullary nails
GMDN: 33187, 38152, 38153

Product category: Bone screws
GMDN: 46647

Product category: Orthopaedic plates
GMDN: 46647

Product category: Pins and wires
GMDN: 32854, 35685, 44854

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 00193/2018, 2018-03-09
OSV 00317/2018, 2018-03-30
OSV 00431/2018, 2018-05-30
OSV 00778/2018, 2018-07-02
OSV 01067/2018, 2018-10-29
OSV 00205/2019, 2019-03-29
OSV 00379/2019, 2019-07-17

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: 2019-06-28

Issue: 2/2019-07-18

Valid until: 2024-05-27



Director of SIQ

Igor Likar