



CERTIFICATE

This certifies that the Quality management system for medical devices of company

Iskra Medical d.o.o.

Registered Office: Stegne 23, 1000 Ljubljana, Republic of Slovenia

Operative Site: Otoče 5a, 4244 Podnart, Republic of Slovenia

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

DESIGN AND DEVELOPMENT, PRODUCTION, SALES AND SERVICING OF ACTIVE (NON-IMPLANTABLE) UTILIZING NON-IONIZING RAYS - DEVICES FOR ELECTROTHERAPY, ULTRASOUND THERAPY, LASER - AND PHOTOTHERAPY, LYMPHDRAINAGE, VACCUM THERAPY, MAGNETOTHERAPY, THERMOTHERAPY AND RELATED ACCESSORIES

Certificate No.: M-0211/21

Date of issuance: April 8th, 2021

Original date of approval: June 15th, 2009

This certificate is valid from April 8th, 2021 to April 7th, 2024 on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic



Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices.