





CERTIFICATE

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

BIONIK Stapro Group s.r.o.

Seat: Pernštýnské náměstí 51, 530 02 Pardubice, Czech Republic Operative Site: 17. listopadu 512, 530 02 Pardubice, Czech Republic

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

EN ISO 13485:2016

for the following scope:

SUPPLYING OF ACTIVE MEDICAL DEVICES, NON-ACTIVE IMPLANTS
AND IN VITRO REAGENTS
SERVICING OF ACTIVE MEDICAL DEVICES

Certificate No.: M-0539/23

Date of issuance: February 1st, 2023

Original date of approval: February 1st, 2023

This certificate is valid from February 1st, 2023 to January 31st, 2026 on condition that organization will maintain effective quality management system. 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

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 covered by EA MLA and IAF MLA.