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SNAS
Reg. No. 305/R-064

CERTIFICATE

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

DINA-HITEX spol. s r.o.

Seat: Ždánská 987, 685 01 Bučovice, Czech Republic
Operational site: Nad Tratí 427, 684 01 Hodějice, Czech Republic

DINA - HITEX®

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

EN ISO 13485:2016

for the following scope:

THE DESIGN, MANUFACTURE, SALES AND DISTRIBUTION OF STERILE AND NON-STERILE MEDICAL DEVICES:
SURGICAL DRAPES, SURGICAL GOWNS, DEVICE COVERS, COLLECTION POUCHES, FIXATION ELEMENTS, ABSORBENT TOWELS
AND NON-STERILE PROTECTIVE DEVICES AND UMBILICAL CORD BAND

ASSEMBLING OF STERILE PROCEDURAL PACKS

STERILIZATION OF MEDICAL DEVICES AS PER EN ISO 11135:2014

Certificate No.: M-0545/23 **Date of issuance: July 24th, 2023** **Original date of approval: July 24th, 2023**

This certificate is valid from **July 24th, 2023** to **July 23rd, 2026** 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 covered by EA MLA and IAF MLA.

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