



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 Trati 427, 684 01 Hodějice, 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:

**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.