

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 243575-2017-AQ-CZE-NA-PS rev.3.0 Project No.: PRJC-56910-2008-MS-CZE Initial Certification Date: 25 August, 2005 Valid Until: 19 September, 2023

This is to certify that the management system of:

## **DINA - HITEX, spol. s.r.o.**

Ždánská 987, 685 01 Bučovice Czech Republic

With sites as listed overleaf.

Complies with the requirements of:

### **ISO 13485:2016/NS-EN ISO 13485:2016**

The Certificate is valid for the following scope:

**THE DESIGN, MANUFACTURE, SALES AND DISTRIBUTION OF STERILE MEDICAL DEVICES: DRAPES, GOWNS, COVERS, POUCHES, FIXATION ELEMENTS, PROTECTIVE CLOTHES, ABSORBENT TOWELS, UMBILICAL CORD BANDS, INCISION FILMS, WOUND CARE PRODUCTS, APPLICATORS, PLASTIC INSTRUMENTS, LIGHT HANDLE COVERS, OPHTHALMIC STRIPS; NON-STERILE MEDICAL DEVICES: DRAPES, GOWNS, EQUIPMENT COVERS, POUCHES, FIXATION ELEMENTS AND PROTECTIVE CLOTHES FOR BARRIER SYSTEM; ASSEMBLING OF STERILE PROCEDURAL PACKS. STERILIZATION OF MEDICAL DEVICES AS PER EN ISO 11135:2014.**

Place and date:  
Høvik, 23 September 2020

For:  
DNV GL PRESAFE AS



Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see [www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)

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Site Name	Address	Site Scope
DINA - HITEX, spol. s.r.o.	Ždánská 987, 685 01 Bučovice Czech Republic	The design, manufacture, sales and distribution of sterile medical devices: drapes, gowns, covers, pouches, fixation elements, protective clothes, absorbent towels, umbilical cord bands, incision films, wound care products, applicators, plastic instruments, light handle covers, ophthalmic strips; non-sterile medical devices: drapes, gowns, equipment covers, pouches, fixation elements and protective clothes for barrier system; assembling of sterile procedural packs. Sterilization of medical devices as per EN ISO 11135:2014.
DINA - HITEX, spol. s.r.o.	Nová 958, 68501 Bučovice, Czech Republic	Manufacture of disposable non-sterile medical devices.

End of Certificate

