MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

America

CERTIFICATE

No. QS6 067069 0028 Rev. 00

Certificate Holder:

LINET spol. s r.o.
Želevcice 5
274 01 Slaný
CZECH REPUBLIC

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing, Distribution, Servicing and Installation of Hospital Beds, Nursing Beds, Birthing Beds, ICT Solutions, Transport Stretchers, Anti-Decubitus Systems and Mattresses and Furniture for the areas of Hospital Care, Gynaecology, Social Care and Home Care**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **64-454-4504**

Effective Date: **2018-09-17**

Expiry Date: **2021-09-16**

Date of Issue: 2018-09-21

(Arie Henkin)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
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TÜV SÜD America

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Regulatory Requirements: Audit/Certification Criteria

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Facility(ies):

LINET spol. s r.o.
Politických veznu 1969, 27401 Slaný, CZECH REPUBLIC

LINET spol. s r.o.
Želevcice 5, 274 01 Slaný, CZECH REPUBLIC

Facility Scopes:

Linet spol. s.r.o.
Politických vězňů 1969, Slaný, 274 01, CZECH REPUBLIC

Manufacturing of Hospital Beds and Nursing Beds, for the areas of Hospital Care, Gynaecology, Social Care and Home Care
DUNS No: 49-609-1110

Linet spol. s.r.o.
Želevčice 5, 274 01 Slaný, CZECH REPUBLIC

Design and Development, Manufacturing, Distribution, Servicing and Installation of Hospital Beds, Nursing Beds, Birthing Beds, ICT Solutions, Transport Stretchers, Anti-Decubitus Systems and Mattresses and Furniture for the areas of Hospital Care, Gynaecology, Social Care and Home Care
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TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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