



America

CERTIFICATE

No. QS6 067069 0028 Rev. 02

Certificate Holder:

LINET

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

Certification Mark:



Scope of Certificate:

Design, Development, Manufacture, Distribution, Servicing and Installation of Hospital Beds, Nursing Beds, Birthing Beds, ICT Solutions, Stretchers, Anti-Decubitus Systems and Mattresses and Furniture for the areas of Hospital Care, Gynecology, Social Care and Home Care

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. 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 www.tuvsud.com/ps-cert

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

REPs Facility ID:

F002178

Effective Date:

2021-09-29

Expiry Date:

2022-09-16

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Date of Issue: 2021-10-06

(Michael Ogunleye)
 Manager, US Certification Body,
 Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

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

LINET spol. s r.o.
Politických veznu 1969, 274 01 Slaný, CZECH REPUBLIC

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Facility Scopes:

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Manufacturing of Hospital Beds and Nursing Beds for the areas for Hospital Care, Gynaecology, Social Care and Home Care
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