

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

- 1) No. 58/2022 - **Date 06/04/2022**
- 2) Issuer's name: **KSP ITALIA SRL**
Issuer's address: **VIA DELL'ARTIGIANATO 1, 06031 BEVAGNA (PG), ITALY Tel. 0742.36.19.47**
Fax 0742.36.19.46 www.kspitalia.com, e-mail: ksp@kspitalia.com

No. EUDAMED SRN: **IT-MF-000009316**

- 3) Object of the declaration: **SLINGS FOR PATIENT LIFTS N9637-M.**
Intended use: **Device to move patients with disabilities and / or reduced mobility.**
- 4) The Manufacturer KSP Italia declares under his sole responsibility that the medical device above described complies with all applicable requirements of the following legislation and fulfils all applicable provisions thereof :

Documents No.	Title	Edition/Date of issue
5) Regulation (EU) 2017/745	Medical Devices Regulation	Emission: 5 April 2017

Additional information:

- 6) Medical devices designed and manufactured with quality management system compliant to ISO 13485.
CE Marked Medical device in accordance with Annex II and III, Regulation (UE) 2017/745.
Class I medical device as for rule 1, Regulation (UE) 2017/745, Annex VIII.
Registered at the Italian Ministry of Health with respective model number: N9637-M: 2269998 .

BASIC UDI-DI (GMN): 805577318SOLLEV-IMBRSTX3

Signed for and on behalf of:

KSP Italia Srl

Bevagna, 06/04/2022

- 7) **Claudio Emanuelli,**
Legal Representative

