

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

1) No. 54/2022 - 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 WITH HEAD SUPPORT, N9622S - N9622M -N9622L - N9622XL - N9622XXL - N9633S - N9633M -N9633L - N9633XL - N9633XXL -N9636S - N9636M -N9636L - N9633XL**
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:

KSP CODE	N° REG.	KSP CODE	N° REG.	KSP CODE	N° REG.
N9636-S	2270364	N9636-M	2270366	N9636-L	2270368
N9636-XL	2270370	N9633-S	2270091	N9633-M	2270095
N9633-L	2270098	N9633-XL	2270105	N9633-XXL	2270108
N9622-S	2270044	N9622-M	2270050	N9622-L	2270081
N9622-XL	2270086	N9622-XXL	2270087		

BASIC UDI-DI (GMN): 805577318SOLLEV-IMBRTEW8

Signed for and on behalf of:

KSP Italia Srl

Bevagna, 06/04/2022

7) Claudio Emanuelli,
Legal Representative

