KSP ITALIA

KSP ITALIA s.r.l.
Via dell'Artigianato, 1
06031 Bevagna (PG) - Italy
Tel. +39 0742 361947
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Capitale Sociale € 10.400,00 i.v. - REA n.160010
Iscr. Registro Imprese di Perugia n. 01793970540
Codice Fiscale / Partita Iva 01793970540
la società non è in stato di liquidazione

ksp@kspitalia.com
www.kspitalia.com

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

1) No. 030/24 - **Date 14/02/2024**

2) Issuer's name: KSP ITALIA SRL
Issuer's adress: **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**

N° EUDAMED SRN: **IT-MF-000009316**

3) Object of the declaration: **ELECTRIC PATIENT LIFTER GEMINI, model N715/170.**
Intended use: Assistive medical device for lifting and transferring elderly and/or disabled people.

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 (and any other relevant UE legislation providing for the issuance of EU declaration of conformity):

Documents No.	Title	Edition/Date of issue
5) Regulation (EU) 2017/745	Medical Devices Regulation	Emission: 5 April 2017
Directive 2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment	Emission: 8 June 2011

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 Annex III, Regulation (UE) 2017/745.
Class I medical device as for rule 1 and rule 13, Regulation (UE) 2017/745, Annex VIII.
Registered at the Italian Ministry of Health with number: **N715/170: 2272691**.

BASIC UDI-DI (GMN): **805577318SOLLEVAT-ELETZD**

Signed for and on behalf of:

KSP Italia Srl

Bevagna, li 14/02/2024

KSP ITALIA srl
Via dell'Artigianato, 1
06031 BEVAGNA (PG)
Tel. 0742.361947 Fax 0742.361945

7) **Claudio Emanuelli,**
Legal Representative

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