KSP ITALIA S.r.l.

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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
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Declaration of Conformity
(in accordance with ISO/IEC 17050-1)

1) No. 272/2021 - **Date 16/06/2021**

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

No. EUDAMED SRN: XXXXXXXXXX

3) Object of the declaration: **ELETRIC PATIENT LIFTER GEMINI, models N715/170 – N715/200**

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
	Regulation 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, 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 numbers:
N715/170: 1354700, N715/200: 1509819.

BASIC UDI (GMN): 805577318SOLLEVAT-ELETZD

Signed for and on behalf of:

KSP Italia Srl

Bevagna, 16/06/2021

(Place and date of issuance)

7) Claudio Emanuelli,
Legal Representative ....

(Name and function) (Signature or equivalent authorized by the issuer)