

Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

1) No. 184/22- **Date 21/09/2022**

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

N° EUDAMED SRN: **IT-MF-000009316**

3) Object of the declaration: **HYDRAULIC PATIENT LIFTER , models: N305/150 - N505/170 - N705/200**

Intended use: **Medical device for lifting and transferring elderly and 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 :

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 Annex 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 number:
N305/150: 2272642, N505/170: 2272680, N705/200: 2272767.

BASIC UDI-DI (GMN): **805577318SOLLEVAT-OLEO3C**

Signed for and on behalf of:

KSP Italia Srl

Bevagna, li 21/09/2022

7) Claudio Emanuelli,
Legal Representative



(Signature or equivalent authorized by the issuer)