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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 336/22 - **Date 12/10/2022**

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: **IT-MF-000009316**

3) Object of the declaration: **FLEBO-HOLDER ROD, A9021.**
Intended use: **Support for flebo in hospital, home or community environments.**

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 informations:

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, model and correspondent number: 2273337.

BASIC UDI-DI (GMN): **805577318ACC-LETTO-SUP65**

Signed for and on behalf of:

KSP Italia Srl

Bevagna, 12/10/2022

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