



GPS s.r.l. - Società Uninomiale
Via Castel Vaglietti n.4 – 24011 Almè (BG) Italy
Tel. ++39-035-4376456 - Fax++39-035-617844
E-mail: gps@gpsmedical.com
PEC: gpsmedical@ribopec.it
<http://www.gpsmedical.com>
C.F./P.IVA/ISCR.REG.IMPRESE DI BG n.01672950167
REA BG n.228103

DECLARATION OF CONFORMITY

The society GPS S.R.L. Unipersonale (SRN code n.IT-MF-000011321), with registered and operational headquarters in Almè (BG), Via Castel Vaglietti n.4, as manufacturer

DECLARES

under its sole responsibility that the medical device named

**UMBILICAL CORD CLAMP DISPOSABLE STANDARD SIZE IN
CONF. SINGLE - BOX OF 500 PCS.**

**REF. 0111 - CND V0202 - REPERTORY 11773 - GMDN 32192
UDI-DI Basic 805572727PinOmbelico1113L**

It belongs to the sterile risk class I, in accordance with rule 4 of Annex IX of Directive 93/42 / EEC (and the applicable requirements of EU regulation 2017/745) and subsequent amendments. (amended by Dir. 2007/47 / EC), implemented in Italy with Legislative Decree 24 February 1997, n. 46, and subsequent amendments (amended by Legislative Decree no. 37/10):

- **complies with** the essential requirements and provisions of Directive 93/42 / EEC (and the applicable requirements of EU regulation 2017/745) and subsequent amendments and additions. as per Technical File no. FT.001.GP filed at the Company
- **is manufactured** in accordance with the Quality System that meets the requirements set out in Annex II of the aforementioned legislative decree, as per Certificate no. QCT-0120-19 issued on 21/05/2019 with expiry 20/05/2024 by the Istituto Superiore di Sanità - Viale Regina Elena n. 299 - 00161 ROME - Notified Body n. 0373.
- **It is sterile** - Ethylene Oxide Sterilization.

Almè, 22 february 2022

Il Rappresentante Legale
Giacometti Ernesto