



GPS s.r.l. - Società Uninomiale
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C.F./P.IVA/ISCR.REG.IMPRESA DI BG n.01672950167
REA BG n.228103

Almè , 10 January 2022

DECLARATION OF CONFORMITY

The undersigned Mr Ernesto Giacometti who was born in Milan on 19th May 1961, as General Manager of Company GPS S.r.l.u.(cod. SRN no. IT-MF-000011321) - located in Almè (BG) Italy, Via Castel Vaglietti no. 4 ; VAT no. IT01672950167 - and as manufacturer of the following products:

DISPOSABLE VAGINAL SPECULUM WITH CENTRAL PIN
REF. 0104 SPECULUM SMALL SIZE
REF.0104/S SPECULUM MEDIUM/SMALL SIZE
REF. 0105 SPECULUM MEDIUM SIZE
REF.0105/S SPECULUM MEDIUM SIZE
REF. 0106 LARGE SIZE SPECULUM
CND U089006 GMDN 37468 REPERTOIRE 11770
UDI-DI BASIC 805572727SpecScrewPernoGS

DECLARES

that said products:

- **Belongs to** the class I sterile, in accordance with the rule 5 of the annex IX of 93/42 EEC Directive enforced in Italy by the Decretal Legislative 46 issued February 24, 1997 and subsequent amendments (and the applicable requirements of EU regulation 2017/745)
- **are products** in conformity with the essential requirements and order of 93/42/EEC directive (and the applicable requirements of EU regulation 2017/745), as per Technical File FT.001.GP.
- **are fabricated** in accordance with the Quality Assurance System which meets the requirements of the Annex II of the above-mentioned Directive and as per Certificate **QCT-0120-19** issued 21/05/2019 expire 20/05/2024 release by the Institute Superior di Sanity, Notified Body 0373.
- **Are sterile.** Sterilized with ethylene oxide.

Sincerely,

GPS S.R.L.
L'AMMINISTRATORE UNICO
Ernesto Giacometti