

EU DECLARATION OF CONFORMITY

Manufacturer: Disposable Medical Instruments Ltd.

- **Address:** 15a Hillside Business Park, Hillside Road, Bury St Edmunds, Suffolk IP32 7EA, UK
- **SRN:** GB-MF-000016735

EU Authorised Representative: Disposable Medical Instruments (Ireland) Ltd.

- **Address:** Bridge Street, Munnilly, Cootehill, County Cavan, Ireland, H16 TH26
- **SRN:** IE-AR-000014747

Medical Devices:

PP16073	Fine Suture Pack Plus
PP16259	IUD Kit
PP16265	IUD Pack
PP16284	IUD Pack
PP16286	IUD Pack
PP16339	IUD Kit Small
PP16363	IUD Kit
PS10001	Cusco Vaginal Speculum XSmall
PS10002	Cusco Vaginal Speculum Small
PS10003	Cusco Vaginal Speculum Medium
PS11003	Ramplsey Sponge Holding Forceps
PS12004	Mayo Needle Holder
PS13008	Hook Retriever Thread IUD
PS13016	Galabin Uterine Sound Fully Flexible
PS14007	Sims Curette 7.5mm
PS14011	Sims Curette 4mm
PS5003	Spencer Wells Forceps Straight 20cm
PS5019	Teale Vulsellum Uterine Forceps CVD 23cm
PS5028	Luer Tenaculum Forceps 24cm
PS5046	Hartmann Crocodile Forceps 20cm
PS5057	Spencer Wells Forceps Curved 15cm
PS5097	Gross Maier Forceps 25cm
PS5098	Luer Tenaculum Forceps 18cm
PS5099	Spencer Wells Forceps CVD 20cm
PS5101	Luer Tenaculum Forceps Fine 24cm
PS5103	Luer Tenaculum Forceps Fine 18cm
PS5104	Hartmann Crocodile Forceps Fine 20cm
PS7021	McIndoe Scissors Straight 18cm
PS7023	McIndoe Scissors Curved 18cm
PS7056	McIndoe Scissors Straight 22cm
PS8001	Dilator Cervix 3/4 22cm
PS8002	Dilator Cervix 5/6 22cm
PS8008	Dilator Cervix 7/8mm
PS8009	Dilator Cervix 9/10mm
PS8010	Dilator Cervix 11/12mm

Generic GS1 UDI: (01) 5 0563659 XXXXX 8 (17) XXXXXX (10) XXXXXXX
(01) 5 50605447 XXXXX 8 (17) XXXXXX (10) XXXXXXX

Risk Classification: Disposable Medical Instruments Ltd. hereby declares that the devices described above have been classified as Class IIa and sterile in accordance with Annex VIII of the MDR (EU) 2017/745.

Intended Use: Sterile, single-use invasive surgical instruments (through body orifice).

Quality Management System Certificates:

- Current Certificate ISO 13485:2016 Ref: GB17/873585,
Under the Supervision of Notified Body Number 0120
SGS UK Ltd, 202b Worle Parkway, Weston-Super-Mare, BS22 6WA, UK
- Current Certificate Directive 93/42/EEC Ref: GB19/964368
Under the Supervision of Notified Body Number 1639
SGS House Noorderlaan 87 2030 Antwerp, Belgium

Additional Standards Applied:

Council Directive 93/42/EEC as amended by Directive 2007/47/EC. Conforming with national standards transposing harmonised standards ISO 11135-2014; ISO 15223-2021; BS EN 1041-2008+A1:2013 and subject to the procedure set out in Annex V of Directive 93/42/EEC as amended by Directive 2007/47/EC.

On behalf of Disposable Medical Instruments Ltd, I hereby declare that the devices listed above conform to the requirements of the European MDR (EU) 2017/745.

This declaration is issued under the sole responsibility of the manufacturer and is valid from: **23 Mar 2022**

Authorised Signatory:

On behalf of the Company,



Nigel Scrivener
Operations Manager