EC Declaration of Conformity

Manufacturer's Name:	PMS Tıbbi Cihazlar Teknolojisi Sanayi ve Ticaret A.Ş.
Manufacturer's Address:	Karaduvar Mah. Serbest Bölge 11. Cadde No: 46, Akdeniz, 33020 Mersin/TURKEY Phone: +90 324 238 7042 Fax : +90 324 238 6549 e-mail : pms@pmsmedikal.com
SRN (Single Registration Number):	TR-MF-000016263
Basic UDI-DI:	86989733PMS2021BR
Name of the Devices:	Sterilization Reel (Flat)- (MELAfol branded) Sterilization Pouch (Flat, Gusseted)- (MELAfol branded)
Product code:	ME00501- MELAfol 501 (Flat Pouch, 5 cm x 25 cm, 1000 pcs.) ME00502- MELAfol 502 (Flat Reel, 5 cm x 200 m) ME00751- MELAfol 751 (Flat Pouch, 7,5 cm x 25 cm, 1000 pcs.) ME00752- MELAfol 752 (Flat Reel, 7,5 cm x 200 m) ME01001- MELAfol 1001 (Flat Pouch, 10 cm x 25 cm, 1000 pcs.) ME01002- MELAfol 1002 (Flat Reel, 10 cm x 200 m) ME01502- MELAfol 1502 (Flat Reel, 15 cm x 200 m) ME02002- MELAfol 2002 (Flat Reel, 20 cm x 200 m) ME02502- MELAfol 2502 (Flat Reel, 25 cm x 200 m) ME02051- MELAfol 2051 (Gusseted Pouch, 20 cm x 50 cm, 100 pcs.)
Classification:	Class I-other, (EU) 2017/745 MDR- Annex VIII, Rule 1
Related Standards:	EN 868-5:2019, ISO 11607-1, ISO 11140-1, ISO 13485:2016
Notified Body Address:	N/A
Notified Body Identification number:	N/A
Conformity Assessment Route:	Annex II (Technical Documentation) and Annex III (Technical documentation on post-market surveillance)

This declaration of conformity is under the sole responsibility of PMS Tıbbi Cihazlar Teknolojisi Sanayi ve Ticaret A.Ş. and issued as per Annex IV of (EU) 2017/745 MDR.

We hereby declare that the medical devices specified above meet the provision of the Regulation (EU) 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by Lloyd's Register Quality Assurance Limited.

All supporting documentation is retained at the premises of the manufacturer.

Signed for and on behalf of PMS Tıbbi Cihazlar Teknolojisi Sanayi ve Ticaret A.Ş.

Authority : Taner ERSEN

Function **:** Quality Assurance Manager

Date **:** November 09, 2021

Place **:** Mersin-Turkey

