

EU Declaration of Conformity

According to Annex IV of the Regulation (EU) 2017/745 concerning medical devices, we:

Manufacturer name: Delmont imaging
Manufacturer address: 390 avenue du Mistral, 13600 La Ciotat, FRANCE
Manufacturer SRN: FR-MF-000000157

Declare under our responsibility the medical device (see list below for details and accessories):

Generic name: Sterilization baskets
Classification: I, rule 1
Basic UDI-DI: 37012178STBAL5

Based on the following elements:

Conformity route: Annex II and III the European Regulation (EU) RG 2017/745
Technical file: TF-STBA

We certify and declare that the medical device specified above complies with the requirements of:

- the European Regulation (EU) RG 2017/745 (MDR), of the European Parliament and of the Council of 5 April 2017 on medical devices.

Representative name: MONTILLOT Pierre
Representative function: CEO
Revision date: 2024-08-22
Date of validity: 2026-12-31



Applicable standards

EN 62366-1:2015/A1:2020; EN ISO 10993-1:2020; EN ISO 13485:2016/AC:2018/A11:2021; EN ISO 14971:2019; EN ISO 15223-1:2021; EN ISO 17664-2:2021; EN ISO 17665-1:2006; EN ISO 20417:2021.

REF	UDI-DI	Description
D200 160 003	03701217800113	Sterilisation tube for electrodes
D200 160 023	03701217803879	Sterilisation basket for one endoscope – 450x70x60mm
D200 160 034	03701217803701	Sterilisation tube for bariatric electrodes
D200 160 504	03701217803855	Sterilisation basket with personalized silicone holders - 540x240x70mm - ReseCare (&XXL)
D200 160 505	03701217803848	Sterilisation basket with personalized silicone holders - 540x240x70mm - MaxiCare set
D200 160 507	03701217803831	Sterilisation basket for two instruments - 480x150x50mm
D200 160 508	03701217803824	Sterilisation basket 480x240x70mm with a silicone mat & a lid
D200 160 511	03701217806764	NeoCare XXL sterilisation basket - OP-hysteroscope level
D200 160 512	03701217806771	NeoCare sterilisation basket - 3mm instrumentation level
D200 160 513	03701217806788	NeoCare XXL sterilisation basket - MaxiCare level
D200 160 514	03701217806795	Lid for NeoCare XXL sterilisation basket
D200 160 515	03701217807891	NeoCare XXL complete sterilisation basket with 2 trays and 1 lid
D200 160 516	03701217807983	NeoCare sterilisation basket - OP-hysteroscope level
D200 160 517	03701217807990	NeoCare complete sterilisation basket with 2 trays and 1 lid
D200 160 518	03701217802674	Lid for NeoCare sterilisation basket
D200 160 521	03701217802667	NeoCare complete sterilisation basket with 2 trays and 1 lid
D200 160 522	03701217802605	Sterilisation basket with personalized silicone holders - 540x240x70mm – EasyCare set
D300 190 000	03701217802742	Protective tube for endoscopes
D300 190 002	03701217803695	Sterilisation tube for bariatric endoscope