



EC Declaration of Conformity

According to Annex II Directive 93/42/EEC concerning medical devices amended by the Directive 2007/47/EC

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

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

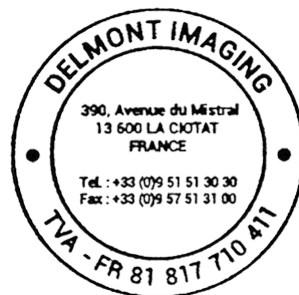
Generic name: Uterine manipulator
Risk classification: IIa, rule 5
Basic UDI-DI: 37012178UTMAML

Based on the following elements:

Conformity route: Annex II point 3 Directive 93/42/CEE
Technical file: TF- UTMA
Notified body: SIQ (1304), Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia
EC certificate: MDD-085

We, the undersigned, certify and declare that the medical device is in conformity with the relevant essential requirements set out in Annex I to Directive 93/42/EEC.

Representative name: MONTILLOT Pierre
Representative function: CEO
Revision date: 2024-08-22



Applicable standards

EN 62366-1:2015/A1:2020; EN ISO 10993-1:2020; EN ISO 10993-10:2013; EN ISO 10993-11:2018; EN ISO 10993-13:2010; EN ISO 10993-12:2021; EN ISO 10993-16:2017; EN ISO 10993-17:2009; EN ISO 10993-18:2020; EN ISO 10993-2:2022; EN ISO 10993-23:2021; EN ISO 10993-5:2010; EN ISO 11138-7:2019; EN ISO 13485:2016/AC:2018/A11:2021; EN ISO 14971:2019; EN ISO 15223-1:2021; EN ISO 17664-1:2021; EN ISO 17665-1:2006; EN ISO 20417:2021; EN ISO 7153-1:2016; ISO 15223-2:2010; ISO/TS 21726:2019; XP ISO/TS 10993-19 :2022

REF	UDI-DI	Description EN
D300 120 100	03701217803602	Handle with Pozzi forceps rotation module for Mangeshikar uterine manipulator
D300 120 101	03701217803596	Outer sheath with fixation nut for Mangeshikar uterine manipulator
D300 120 102	03701217803589	Inner sheath with locking pin for Mangeshikar uterine manipulator
D300 120 103	03701217803572	Sliding sheath to use with cap for Mangeshikar uterine manipulator
D300 120 104	03701217803565	Cap of 35mm with white insulating ring for Mangeshikar uterine manipulator
D300 120 105	03701217803558	Cap of 40mm with white insulating ring for Mangeshikar uterine manipulator
D300 120 106	03701217803541	Cap of 45mm with white insulating ring for Mangeshikar uterine manipulator
D300 120 107	03701217803534	Pozzi forceps for cervical holding, for Mangeshikar uterine manipulator
D300 120 108	03701217803527	Intra-uterine insert 4x40mm for Mangeshikar uterine manipulator
D300 120 109	03701217803510	Intra-uterine insert 5x50mm for Mangeshikar uterine manipulator
D300 120 110	03701217803503	Intra-uterine insert 6x60mm for Mangeshikar uterine manipulator
D300 120 111	03701217803497	Intra-uterine insert 7x70mm for Mangeshikar uterine manipulator
D300 120 112	03701217803138	Intra-uterine insert 8x80mm for Mangeshikar uterine manipulator
D300 120 113	03701217803121	Intra-uterine insert 8x120mm for Mangeshikar uterine manipulator
D300 120 114	03701217803091	Intra-uterine insert 8x150mm for Mangeshikar uterine manipulator