

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:

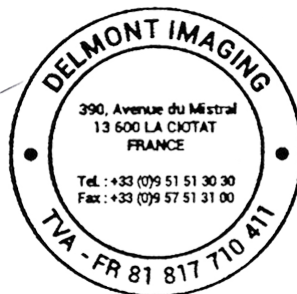
Generic name: Hysteroscopy system
Risk classification: IIa, rule 5
Basic UDI-DI: 37012178HYSSM8

Based on the following elements:

Conformity route: Annex II point 3 Directive 93/42/CEE
Technical file: TF- HYSS
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: 2024-12-22



Applicable standards

EN 62366-1:2015/A1:2020; EN IEC 60601-2-2 :2018; EN ISO 10993-1:2020; EN ISO 10993-10:2013; EN ISO 10993-11:2018; 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/A11:2021; EN ISO 15223-1:2021; EN ISO 17664-1:2021; EN ISO 17665-1:2006; EN ISO 20417:2021; EN ISO 80369-1:2018; ISO/TS 21726:2019; XP ISO/TS 10993-19 :2022

REF	GTIN/UDI-DI	Description EN
D300 110 000	03701217800618	5,5mm outer operating sheath, rotatable stopcock - for 2,9mm 12° or 30° hysteroscope
D300 110 001	03701217800625	4,9mm inner operating sheath, 7Fr. Operative canal - for 2,9mm 12° or 30° hysteroscope
D300 110 002	03701217800632	Diagnostic sheath, 4mm, rotatable stopcock - for 2,9mm 12° or 30° hysteroscope
D300 110 008	03701217800694	Inner diagnostic sheath, 4mm, rotatable stopcock - for 2,9mm 12° or 30° hysteroscope
D300 110 009	03701217800700	Outer diagnostic sheath, 5mm, rotatable stopcock - for use with D300 110 008/011
D300 110 010	03701217800717	Inner diagnostic sheath, 5,4mm, rotatable stopcock - for 4mm 0° or 12° hysteroscope
D300 110 011	03701217800724	Inner diagnostic sheath, 4mm, rotatable stopcock - for 2,9mm 0° hysteroscope
D300 110 012	03701217800731	Inner diagnostic sheath, 5,4mm, rotatable stopcock - for 4mm 30° hysteroscope
D300 110 013	03701217800748	Outer diagnostic sheath, 6,5mm, rotatable stopcock - for use with D300 110 010/012
D300 110 020	03701217800816	Diagnostic sheath, 5mm, rotatable stopcock - for 4mm 12° or 30° hysteroscope
D300 110 021	03701217800823	Diagnostic sheath, 5mm, rotatable stopcock - for 4mm 0° hysteroscope
D300 110 023	03701217800847	Diagnostic sheath, 4mm, rotatable stopcock - for 2,9mm 0° hysteroscope
D300 110 025	03701217800861	Diagnostic sheath, 3mm, rotatable stopcock - for 2mm 30° hysteroscope
D300 110 033	03701217800946	5mm outer operating sheath, rotatable stopcock - for 2,9mm 12° or 30° hysteroscope
D300 110 035	03701217800960	4,3mm inner operating sheath, 5Fr. Operative canal - for 2,9mm 12° or 30° hysteroscope
D300 110 043	03701217801042	3,7mm inner operating sheath, 5Fr. Operative canal - for 2mm 30° hysteroscope
D300 110 044	03701217801059	4,3mm outer operating sheath, rotatable stopcock - for 2mm 30° hysteroscope
D300 110 045	03701217801066	6,5mm outer operating sheath, rotatable stopcock - for 4mm 12° or 30° hysteroscope
D300 110 046	03701217801073	4,5mm inner operating sheath, 5Fr. Operative canal - for 4mm 12° or 30° hysteroscope
D300 110 047	03701217801080	7mm outer operating sheath, rotatable stopcock - for 4mm 12° or 30° hysteroscope
D300 110 048	03701217801097	6,2mm inner operating sheath, 7Fr. Operative canal - for 4mm 12° or 30° hysteroscope
D300 110 049	03701217801103	6,3mm outer operating sheath, rotatable stopcock - for 2,9mm 12° or 30° hysteroscope
D300 110 050	03701217801110	5,5mm inner operating sheath, 9Fr. Operative canal - for 2,9mm 12° or 30° hysteroscope
D300 110 053	03701217801141	Standard obturator for 4mm, single or double flow, diagnostic sheath
D300 110 054	03701217801158	Standard obturator for 5mm, single or double flow, diagnostic sheath
D300 110 072	03701217807853	Diagnostic sheath, 4mm, rotatable stopcock - for 2,9mm 395mm XXL hysteroscope
D300 120 000	03701217801196	Graduated scissors, semi-rigid, 7Fr. L: 340mm. Single action jaw
D300 120 001	03701217801202	Graduated forceps (alligator), semi-rigid, 7Fr. L: 340mm. Double action jaws

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D300 120 002	03701217801219	Graduated biopsy forceps, semi-rigid, 7Fr. L: 340mm. Double action jaws
D300 120 003	03701217801226	Graduated IUD grasping forceps, semi-rigid, 7Fr. L: 340mm. Double action jaws
D300 120 004	03701217801233	Graduated scissors, semi-rigid, 5Fr. L: 340mm. Single action jaw
D300 120 005	03701217801240	Graduated forceps (alligator), semi-rigid, 5Fr. L: 340mm. Double action jaws
D300 120 006	03701217801257	Graduated biopsy forceps, semi-rigid, 5Fr. L: 340mm. Double action jaws
D300 120 007	03701217801264	Graduated IUD grasping forceps, semi-rigid, 5Fr. L: 340mm. Double action jaws
D300 120 008	03701217802858	Semi-rigid scissors 7Fr 340mm single action jaw, with flushing port
D300 120 009	03701217802865	Semi-rigid alligator forceps 7Fr 340mm, with flushing port
D300 120 010	03701217802872	Semi-rigid biopsy forceps, 7Fr 340mm, with flushing port
D300 120 011	03701217802889	Semi-rigid IUD grasping forceps 7Fr 340mm, with flushing port
D300 120 012	03701217802902	Semi-rigid scissors 5Fr, 340mm single action jaw, with flushing port
D300 120 013	03701217802919	Semi-rigid alligator forceps 5Fr, 340mm, with flushing port
D300 120 014	03701217802926	Semi-rigid biopsy forceps, 5Fr 340mm, with flushing port
D300 120 015	03701217802933	Semi-rigid IUD grasping forceps 5Fr 340mm, with flushing port
D300 120 060	03701217807389	Semi-rigid scissors, sharp tips, 5Fr., 370mm, rotative, single action jaw, with flushing port
D300 120 061	03701217807372	Semi-rigid scissors, blunt tips, 5Fr., 370mm, rotative, single action jaw, with flushing port
D300 120 062	03701217807365	Semi-rigid biopsy forceps, 5Fr., 370mm, rotative, double action jaws, with flushing port
D300 120 063	03701217807358	Semi-rigid alligator forceps, 5Fr., 370mm, rotative, double action jaws, with flushing port
D300 120 064	03701217807341	Semi-rigid pozzi forceps, 5Fr., 370mm, rotative, double action jaws, with flushing port
D300 120 065	03701217807433	Semi-rigid scissors, sharp tips, 7Fr., 370mm, rotative, single action jaw, with flushing port
D300 120 066	03701217807426	Semi-rigid scissors, blunt tips, 7Fr., 370mm, rotative, single action jaw, with flushing port
D300 120 067	03701217807419	Semi-rigid biopsy forceps, 7Fr., 370mm, rotative, double action jaws, with flushing port
D300 120 068	03701217807402	Semi-rigid alligator forceps, 7Fr., 370mm, rotative, double action jaws, with flushing port
D300 120 069	03701217807396	Semi-rigid pozzi forceps, 7Fr., 370mm, rotative, double action jaws, with flushing port
D300 120 070	03701217809369	Complete handle for semi-rigid shaft with rotation module
D300 120 071	03701217809451	Semi-rigid scissors, sharp tips, 5Fr., 370mm, rotative, single action jaw, with flushing port. Shaft only.
D300 120 072	03701217809437	Semi-rigid scissors, blunt tips, 5Fr., 370mm, rotative, single action jaw, with flushing port. Shaft only.
D300 120 073	03701217809390	Semi-rigid alligator forceps, 5Fr., 370mm, rotative, double action jaws, with flushing port. Shaft only.
D300 120 074	03701217809420	Semi-rigid biopsy forceps, 5Fr., 370mm, rotative, double action jaws, with flushing port. Shaft only.

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D300 120 075	03701217809376	Semi-rigid pozzi forceps, 5Fr., 370mm, rotative, double action jaws, with flushing port. Shaft only.
D300 120 076	03701217809468	Semi-rigid scissors, sharp tips, 7Fr., 370mm, rotative, single action jaw, with flushing port. Shaft only.
D300 120 077	03701217809444	Semi-rigid scissors, blunt tips, 7Fr., 370mm, rotative, single action jaw, with flushing port. Shaft only.
D300 120 078	03701217809406	Semi-rigid alligator forceps, 7Fr., 370mm, rotative, double action jaws, with flushing port. Shaft only.
D300 120 079	03701217809413	Semi-rigid biopsy forceps, 7Fr., 370mm, rotative, double action jaws, with flushing port. Shaft only.
D300 120 080	3701217809383	Semi-rigid pozzi forceps, 7Fr., 370mm, rotative, double action jaws, with flushing port. Shaft only.
D300 195 000	03701217805231	Reusable sealing cap for operative sheath