



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: Rigid endoscopes
Risk classification: IIa, rule 7
Basic UDI-DI: 37012178ENDOH7

Based on the following elements:

Conformity route: Annex II point 3 Directive 93/42/CEE
Technical file: TF-ENDO
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

A handwritten signature in black ink, appearing to be 'P. Montillot', is written over a light grey wavy background.



Applicable standards

EN 60601-1:2006/A1:2014 2006/A12:2016 2006/A2:2021; EN 60601-1-6:2010; EN 60601-2-18:2016; EN 62366-1:2015/A1:2020; EN ISO 10993-1:2020; EN ISO 10993-10:2013; EN ISO 10993-12:2012; EN ISO 10993-18:2020; EN ISO 10993-5:2009; EN ISO 13485:2016/AC:2018; EN ISO 14971:2019; EN ISO 15223-1:2021; EN ISO 17664-1:2021 EN ISO 7153-1:2016; EN ISO 17665-1:2006; EN ISO 20417:2021 ISO 8600:1:2015 ISO 8600:3:2019 ISO 8600:4:2014 ISO 8600:5:2020; ISO 8600:7:2012; ISO/TS 18339:2015; IEC 62471:2006; ISO 15223-2:2010; CEN ISO/TS 17665-2:2009 ISO/TS 17665-3:2013

REF	GTIN/UDI-DI	Description EN
D300 100 000	03701217800168	HD hysteroscope 2,9mm 30° 300mm autoclavable
D300 100 001	03701217800175	HD hysteroscope 4mm 30° 300mm autoclavable
D300 100 002	03701217800182	HD hysteroscope 4mm 12° 300mm autoclavable
D300 100 003	03701217800199	HD hysteroscope 2,9mm 0° 300mm autoclavable
D300 100 004	03701217800205	HD hysteroscope 2,9mm 12° 300mm autoclavable
D300 100 005	03701217800212	HD hysteroscope 4mm 0° 300mm autoclavable
D300 100 007	03701217800236	HD hysteroscope 4mm 70° 300mm autoclavable
D300 100 008	03701217800243	Cystoscope 2,7mm 0° 270mm autoclavable
D300 100 009	03701217800250	Cystoscope 2,7mm 30° 270mm autoclavable
D300 100 011	03701217800274	HD cystoscope 4mm 0° 300mm autoclavable
D300 100 012	03701217800281	HD cystoscope 4mm 12° 300mm autoclavable
D300 100 013	03701217800298	HD cystoscope 4mm 30° 300mm autoclavable
D300 100 014	03701217800304	HD cystoscope 4mm 70° 300mm autoclavable
D300 100 015	03701217800311	HD Mini laparoscope 2.9mm 0° 207mm autoclavable
D300 100 016	03701217800328	HD Mini laparoscope 2.9mm 30° 207mm autoclavable
D300 100 017	03701217800335	4K Laparoscope 5,5mm 0° 300mm autoclavable HM
D300 100 018	03701217800342	4K Laparoscope 5,5mm 30° 300mm autoclavable HM
D300 100 019	03701217800359	4K Laparoscope 5,5mm 45° 300mm autoclavable HM
D300 100 020	03701217800366	HD Laparoscope 5,5mm 0° 300mm autoclavable HM
D300 100 021	03701217800373	HD Laparoscope 5,5mm 30° 300mm autoclavable HM
D300 100 022	03701217800380	HD Laparoscope 5,5mm 45° 300mm autoclavable HM
D300 100 023	03701217800397	4K bariatric laparoscope 5.5mm 0° 424mm autoclavable HM
D300 100 024	03701217800403	4K bariatric laparoscope 5.5mm 30° 424mm autoclavable HM
D300 100 025	03701217800410	4K bariatric laparoscope 5.5mm 45° 424mm autoclavable HM
D300 100 026	03701217800427	HD bariatric laparoscope 5.5mm 0° 424mm autoclavable HM
D300 100 027	03701217800434	HD bariatric laparoscope 5.5mm 30° 424mm autoclavable HM
D300 100 028	03701217800441	HD bariatric laparoscope 5.5mm 45° 424mm autoclavable HM
D300 100 029	03701217800458	4K Laparoscope 10mm 0° 330mm autoclavable
D300 100 030	03701217800465	4K Laparoscope 10mm 30° 330mm autoclavable

REF	GTIN/UDI-DI	Description EN
D300 100 031	03701217800472	4K Laparoscope 10mm 45° 330mm autoclavable
D300 100 032	03701217800489	HD Laparoscope 10mm 0° 330mm autoclavable
D300 100 033	03701217800496	HD Laparoscope 10mm 30° 330mm autoclavable
D300 100 034	03701217800502	HD Laparoscope 10mm 45° 330mm autoclavable
D300 100 035	03701217800519	4K bariatric laparoscope 10mm 0° 450mm autoclavable
D300 100 036	03701217800526	4K bariatric laparoscope 10mm 30° 450mm autoclavable
D300 100 037	03701217800533	4K bariatric laparoscope 10mm 45° 450mm autoclavable
D300 100 038	03701217800540	HD bariatric laparoscope 10mm 0° 450mm autoclavable
D300 100 039	03701217800557	HD bariatric laparoscope 10mm 30° 450mm autoclavable
D300 100 040	03701217800564	HD bariatric laparoscope 10mm 45° 450mm autoclavable
D300 100 041	03701217800571	Operating laparoscope 10mm 0° 270mm, non-autoclavable, 45° angulated eyepiece with 5.1mm working channel
D300 100 042	03701217800588	Operating laparoscope 10mm 0° 270mm, non-autoclavable, 90° angulated eyepiece with 5.1mm working channel
D300 100 043	03701217800595	Operating laparoscope 11mm 0° 270mm, non-autoclavable, 45° angulated eyepiece with 6.1mm working channel
D300 100 044	03701217800601	Operating laparoscope 11mm 0° 270mm, non-autoclavable, 90° angulated eyepiece with 6.1mm working channel
D300 100 049	03701217806115	NeoCare - Operative hysteroscope 6mm 12° autoclavable WC 3,6mm
D300 100 051	03701217805460	NeoCare XXL - Operative hysteroscope 9mm 12° autoclavable WC 4,5mm
D300 100 052	03701217803480	Sinuscope 2.7mm 0° 140mm autoclavable
D300 100 053	03701217803473	Sinuscope 2.7mm 30° 140mm autoclavable
D300 100 054	03701217803466	Sinuscope 2.7mm 70° 140mm autoclavable
D300 100 055	03701217803459	Sinuscope 2.7mm 0° 195mm autoclavable
D300 100 056	03701217803442	Sinuscope 2.7mm 30° 195mm autoclavable
D300 100 057	03701217803435	Sinuscope 2.7mm 70° 195mm autoclavable
D300 100 058	03701217803428	Sinuscope 3mm 0° 150mm autoclavable
D300 100 059	03701217803411	Sinuscope 3mm 30° 150mm autoclavable
D300 100 060	03701217803404	Sinuscope 3mm 45° 150mm autoclavable
D300 100 061	03701217803398	Sinuscope 3mm 70° 150mm autoclavable
D300 100 062	03701217803381	HD Sinuscope 4mm 0° 185mm autoclavable
D300 100 063	03701217803374	HD Sinuscope 4mm 30° 185mm autoclavable
D300 100 064	03701217803367	HD Sinuscope 4mm 45° 185mm autoclavable
D300 100 065	03701217803350	HD arthroscope 4mm 70° 185mm autoclavable
D300 100 073	03701217803275	Micro laryngoscope 4mm 70° 185mm autoclavable, reversed light post
D300 100 074	03701217803268	Laryngoscope 6mm 70° 160mm autoclavable HM
D300 100 075	03701217803251	Laryngoscope 6mm 70° 160mm autoclavable
D300 100 076	03701217803244	Laryngoscope 10mm 70° 159mm autoclavable

REF	GTIN/UDI-DI	Description EN
D300 100 077	03701217803237	Laryngoscope 10mm 90° 159mm autoclavable
D300 100 078	03701217803220	Otoscope 1.9mm 0° 100mm autoclavable
D300 100 079	03701217803213	Otoscope 1.9mm 30° 100mm autoclavable
D300 100 080	03701217803206	Otoscope 2.7mm 0° 75mm autoclavable
D300 100 081	03701217803190	Otoscope 2.7mm 30° 75mm autoclavable
D300 100 082	03701217803183	Otoscope 2.7mm 70° 75mm autoclavable
D300 100 083	03701217803176	Otoscope 4mm 0° 50mm non-autoclavable
D300 100 084	03701217803169	Otoscope 4mm 30° 50mm non-autoclavable
D300 100 085	03701217803152	Arthroscope 1.9mm 0° 60mm autoclavable
D300 100 086	03701217803145	Arthroscope 1.9mm 30° 60mm autoclavable
D300 100 087	03701217806474	HD bariatric hysteroscope 2,9mm, 12°, 395mm autoclavable
D300 100 088	03701217806535	HD bariatric hysteroscope 2,9mm, 30°, 395mm autoclavable
D300 100 090	03701217808690	HD hysteroscope 2mm 30° 260mm autoclavable
D300 195 002	03701217802896	Internal sealing valves for NeoCare XXL hysteroscopes
D300 195 003	03701217803015	Internal sterile sealing valves for operative hysteroscopes