

Déclaration CE de Conformité / EC Declaration of Conformity

Selon Annexe II Directive 93/42/CEE relative aux dispositifs médicaux amendée par la Directive 2007/47/CE.
According to Annex II Directive 93/42/EEC concerning medical devices amended by the Directive 2007/47/EC.

Fabricant/*Manufacturer:* DELMONT IMAGING
Adresse de fabrication/*Manufacturer's address* : 390 avenue du Mistral, 13600 La Ciotat, France

Nom du dispositif : Endoscopes rigides et accessoires
Name of device : *Rigid Endoscopes and accessories*

Caractéristiques : Voir Annexe
Characteristics : *See Annex*

Classe du dispositif/*Class of device*: IIa
Règle/*Rule* : 7 Annexe IX 93/42 CEE *Annex IX 93/42/EEC*

Cette Déclaration est basée sur les éléments suivants/*This Declaration is based on the following elements*:
Dossier Technique/*Technical File*: TF-ENDO

Attestation CE d'approbation du Système Qualité : Annexe II point 3 Directive 93/42/CEE
EC Certificate for approbation Quality System: Annex II section 3 Directive 93/42/EEC

Organisme Notifié/*Notified Body* : SIQ (1304)
Mašera-Spasičeva ulica 10, SI-1000 Ljubljana, Slovenia

Attestation/*Certificate*: N° MDD-085 (Valide jusqu'à /*Valid until* 2024-05-26)

Nous soussignons, assurons et déclarons que le dispositif médical défini ci-dessus est conforme aux exigences essentielles applicable, énoncées à l'annexe I de la Directive 93/42/CEE, aussi bien qu'aux dispositions du Code de la Santé Publique Français qui lui sont applicables.

We, the undersigned, certify and declare that the medical device specified above complies with to the essential requirements, applicable, written in annex I Directive 93/42/EEC, and to legal provisions of French Public Health Code, which are applicable.

Date, lieu/ *Date, location* :
2022-06-30, La Ciotat

Cachet de la Société/ *Stamp of the Company*:

Le Président/ *CEO*
Pierre MONTILLOT

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RCS Marseille 817 710 411

Normes Applicables / 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	UID-ID	EN	FR	UMDNS
D300 100 000	03701217800168	HD Hysteroscope 2.9 mm autoclavable 30°	Hystéroscope HD 2,9mm 30° 300mm autoclavable	20-475
D300 100 001	03701217800175	Hysteroscope 4.0 mm autoclavable 30°	Hystéroscope HD 4mm 30° 300mm autoclavable	20-475
D300 100 002	03701217800182	Hysteroscope 4.0 mm autoclavable 12°	Hystéroscope HD 4mm 12° 300mm autoclavable	20-475
D300 100 003	03701217800199	HD Hysteroscope 2.9 mm autoclavable 0°	Hystéroscope HD 2,9mm 0° 300mm autoclavable	20-475
D300 100 004	03701217800205	HD Hysteroscope 2.9 mm autoclavable 12°	Hystéroscope HD 2,9mm 12° 300mm autoclavable	20-475
D300 100 005	03701217800212	HD Hysteroscope 4mm autoclavable 0°	Hystéroscope HD 4mm 0° 300mm autoclavable	20-475
D300 100 006	03701217800229	Hysteroscope 2.7 mm autoclavable 30°	Hystéroscope 2,7mm 30° 270mm autoclavable	20-475
D300 100 007	03701217800236	HD Hysteroscope 4.0 mm autoclavable 70°	Hystéroscope HD 4mm 70° 300mm autoclavable	20-475
D300 100 008	03701217800243	Hysteroscope 2.7 mm autoclavable 0°	Hystéroscope 2,7mm 0° 270mm autoclavable	20-475
D300 100 009	03701217800250	Cystoscope 2.7 mm autoclavable 0°	Cystoscope 2,7mm 0° 270mm autoclavable	20-475
D300 100 010	03701217800267	Cystoscope 2.7 mm autoclavable 30°	Cystoscope 2,7mm 30° 270mm autoclavable	20-475
D300 100 011	03701217800274	HD Cystoscope 4.0 mm autoclavable 0°	Cystoscope HD 4mm 0° 300mm autoclavable	20-475
D300 100 012	03701217800281	HD Cystoscope 4.0 mm autoclavable 12°	Cystoscope HD 4mm 12° 300mm autoclavable	20-475
D300 100 013	03701217800298	HD Cystoscope 4.0 mm autoclavable 30°	Cystoscope HD 4mm 30° 300mm autoclavable	20-475
D300 100 014	03701217800304	HD Cystoscope 4.0 mm autoclavable 70°	Cystoscope HD 4mm 70° 300mm autoclavable	20-475
D300 100 015	03701217800311	HD Mini Laparoscope 2.9 mm autoclavable 0°	Mini laparoscope HD 2,9mm 0° 207mm autoclavable	20-475
D300 100 016	03701217800328	HD Mini Laparoscope 2.9 mm autoclavable 30°	Mini laparoscope HD 2,9mm 30° 207mm autoclavable	20-475
D300 100 017	03701217800335	HD3 Laparoscope 5.5 mm autoclavable 0° HM	Laparoscope HD3 5,5mm 0° 300mm autoclavable HM	20-475
D300 100 018	03701217800342	HD3 Laparoscope 5.5 mm autoclavable 30° HM	Laparoscope HD3 5,5mm 30° 300mm autoclavable HM	20-475
D300 100 019	03701217800359	HD3 Laparoscope 5.5 mm autoclavable 45° HM	Laparoscope HD3 5,5mm 45° 300mm autoclavable HM	20-475
D300 100 020	03701217800366	HD Laparoscope 5.5 mm autoclavable 0° HM	Laparoscope HD 5,5mm 0° 300mm autoclavable HM	20-475
D300 100 021	03701217800373	HD Laparoscope 5.5 mm autoclavable 30° HM	Laparoscope HD 5,5mm 30° 300mm autoclavable HM	20-475
D300 100 022	03701217800380	HD Laparoscope 5.5 mm autoclavable 45° HM	Laparoscope HD 5,5mm 45° 300mm autoclavable HM	20-475
D300 100 023	03701217800397	HD3 Bariatric Laparoscope 5.5 mm autoclavable 0° HM	Laparoscope bariatrique HD3 5,5mm 0° 424mm autoclavable HM	20-475
D300 100 024	03701217800403	HD3 Bariatric Laparoscope 5.5 mm autoclavable 30° HM	Laparoscope bariatrique HD3 5,5mm 30° 424mm autoclavable HM	20-475
D300 100 025	03701217800410	HD3 Bariatric Laparoscope 5.5 mm autoclavable 45° HM	Laparoscope bariatrique HD3 5,5mm 45° 424mm autoclavable HM	20-475
D300 100 026	03701217800427	HD Bariatric Laparoscope 5.5 mm autoclavable 0° HM	Laparoscope bariatrique HD 5,5mm 0° 424mm autoclavable HM	20-475
D300 100 027	03701217800434	HD Bariatric Laparoscope 5.5 mm autoclavable 30° HM	Laparoscope bariatrique HD 5,5mm 30° 424mm autoclavable HM	20-475

REF	UID-ID	EN	FR	UMDNS
D300 100 028	03701217800441	HD Bariatric Laparoscope 5.5 mm autoclavable 45° HM	Laparoscope bariatrique HD 5,5mm 45° 424mm autoclavable HM	20-475
D300 100 029	03701217800458	HD3 Laparoscope 10.0 mm autoclavable 0°	Laparoscope HD3 10mm 0° 330mm autoclavable	20-475
D300 100 030	03701217800465	HD3 Laparoscope 10.0 mm autoclavable 30°	Laparoscope HD3 10mm 30° 330mm autoclavable	20-475
D300 100 031	03701217800472	HD3 Laparoscope 10.0 mm autoclavable 45°	Laparoscope HD3 10mm 45° 330mm autoclavable	20-475
D300 100 032	03701217800489	HD Laparoscope 10.0 mm autoclavable 0°	Laparoscope HD 10mm 0° 330mm autoclavable	20-475
D300 100 033	03701217800496	HD Laparoscope 10.0 mm autoclavable 30°	Laparoscope HD 10mm 30° 330mm autoclavable	20-475
D300 100 034	03701217800502	HD Laparoscope 10.0 mm autoclavable 45°	Laparoscope HD 10mm 45° 330mm autoclavable	20-475
D300 100 035	03701217800519	HD3 Bariatric Laparoscope 10.0 mm autoclavable 0°	Laparoscope bariatrique HD3 10mm 0° 450mm autoclavable	20-475
D300 100 036	03701217800526	HD3 Bariatric Laparoscope 10.0 mm autoclavable 30°	Laparoscope bariatrique HD3 10mm 30° 450mm autoclavable	20-475
D300 100 037	03701217800533	HD3 Bariatric Laparoscope 10.0 mm autoclavable 45°	Laparoscope bariatrique HD3 10mm 45° 450mm autoclavable	20-475
D300 100 038	03701217800540	Bariatric Laparoscope 10.0 mm autoclavable 0°	Laparoscope bariatrique HD 10mm 0° 450mm autoclavable	20-475
D300 100 039	03701217800557	Bariatric Laparoscope 10.0 mm autoclavable 30°	Laparoscope bariatrique HD 10mm 30° 450mm autoclavable	20-475
D300 100 040	03701217800564	Bariatric Laparoscope 10.0 mm autoclavable 45°	Laparoscope bariatrique HD 10mm 45° 450mm autoclavable	20-475
D300 100 041	03701217800571	Operation Laparoscope 10.0 mm non-autoclavable 0° / 1x45° angulated eyepiece, with 5.1 mm working channel	Laparoscope opératoire 10mm 0° oculaire 45° non-autoclavable WC 5,1mm	20-475
D300 100 042	03701217800588	Operation Laparoscope 10.0 mm non-autoclavable 0° / 2x90° angulated eyepiece, with 5.1 mm working channel	Laparoscope opératoire 10mm 0° oculaire 90° non-autoclavable WC 5,1mm	20-475
D300 100 043	03701217800595	Operation Laparoscope 11.0 mm non-autoclavable 0° / 1x45° angulated eyepiece, with 6.1 mm working channel	Laparoscope opératoire 11mm 0° oculaire 45° non-autoclavable WC 6,1mm	20-475
D300 100 044	03701217800601	Operation Laparoscope 11.0 mm non-autoclavable 0° / 2x90° angulated eyepiece, with 6.1 mm working channel	Laparoscope opératoire 11mm 0° oculaire 90° non-autoclavable WC 6,1mm	20-475
D300 100 049	03701217806115	miniCare - Operative hysteroscope 6,5mm 12° autoclavable WC 3,6mm	NeoCare mini Y-Hystéroscope opératoire 6,5mm 12° autoclavable WC3,6mm	20-475
D300 100 051	03701217805460	NeoCare - Operative hysteroscope 9mm 12° autoclavable WC 4,5mm	NeoCare - Hystéroscope opératoire 9mm 12° autoclavable WC 4,5mm	20-475
D300 100 052	03701217803480	Sinuscope 2.7 mm autoclavable 0° 140 mm	Sinuscope 2.7mm 0° 140mm autoclavable	20-475
D300 100 053	03701217803473	Sinuscope 2.7 mm autoclavable 30° 140 mm	Sinuscope 2.7mm 30° 140mm autoclavable	20-475
D300 100 054	03701217803466	Sinuscope 2.7 mm autoclavable 70° 140 mm	Sinuscope 2.7mm 70° 140mm autoclavable	20-475
D300 100 055	03701217803459	Sinuscope 2.7 mm autoclavable 0° 195 mm	Sinuscope 2.7mm 0° 195mm autoclavable	20-475
D300 100 056	03701217803442	Sinuscope 2.7 mm autoclavable 30° 195 mm	Sinuscope 2.7mm 30° 195mm autoclavable	20-475
D300 100 057	03701217803435	Sinuscope 2.7 mm autoclavable 70° 195 mm	Sinuscope 2.7mm 70° 195mm autoclavable	20-475
D300 100 058	03701217803428	Sinuscope 3.0 mm autoclavable 0°	Sinuscope 3mm 0° 150mm autoclavable	20-475
D300 100 059	03701217803411	Sinuscope 3.0 mm autoclavable 30°	Sinuscope 3mm 30° 150mm autoclavable	20-475
D300 100 060	03701217803404	Sinuscope 3.0 mm autoclavable 45°	Sinuscope 3mm 45° 150mm autoclavable	20-475
D300 100 061	03701217803398	Sinuscope 3.0 mm autoclavable 70°	Sinuscope 3mm 70° 150mm autoclavable	20-475

REF	UID-ID	EN	FR	UMDNS
D300 100 062	03701217803381	Sinuscope / Arthroscope HD 4.0 mm autoclavable 0°	Sinuscope HD 4mm 0° 185mm autoclavable	20-475
D300 100 063	03701217803374	Sinuscope / Arthroscope HD 4.0 mm autoclavable 30°	Sinuscope HD 4mm 30° 185mm autoclavable	20-475
D300 100 064	03701217803367	Sinuscope / Arthroscope HD 4.0 mm autoclavable 45°	Sinuscope HD 4mm 45° 185mm autoclavable	20-475
D300 100 065	03701217803350	Sinuscope / Arthroscope HD 4.0 mm autoclavable 70°	Sinuscope HD 4mm 70° 185mm autoclavable	20-475
D300 100 066	03701217803343	Sinuscope / Arthroscope 4.0 mm autoclavable 0°	Sinuscope 4mm 0° 185mm autoclavable	20-475
D300 100 067	03701217803336	Sinuscope / Arthroscope 4.0 mm autoclavable 30°	Sinuscope 4mm 30° 185mm autoclavable	20-475
D300 100 068	03701217803329	Sinuscope / Arthroscope 4.0 mm autoclavable 30° reversed light post	Sinuscope 4mm 30° 185mm autoclavable, pos. lumière inversée	20-475
D300 100 069	03701217803312	Sinuscope / Arthroscope 4.0 mm autoclavable 45°	Sinuscope 4mm 45° 185mm autoclavable	20-475
D300 100 070	03701217803305	Sinuscope / Arthroscope 4.0 mm autoclavable 45° reversed light post	Sinuscope 4mm 45° 185mm autoclavable, pos. lumière inversée	20-475
D300 100 071	03701217803299	Sinuscope / Arthroscope 4.0 mm autoclavable 70°	Sinuscope 4mm 70° 185mm autoclavable	20-475
D300 100 072	03701217803282	Sinuscope / Arthroscope 4.0 mm autoclavable 70° reversed light post	Sinuscope 4mm 70° 185mm autoclavable, pos. lumière inversée	20-475
D300 100 073	03701217803275	Micro laryngoscope 4.0 mm autoclavable 70° reversed light post	Micro laryngoscope 4mm 70° 185mm autoclavable, pos. lumière inversée	20-475
D300 100 074	03701217803268	Laryngoscope 6.0 mm autoclavable 70° HM	Laryngoscope 6mm 70° 160mm autoclavable HM	20-475
D300 100 075	03701217803251	Laryngoscope 6.0 mm autoclavable 70°	Laryngoscope 6mm 70° 160mm autoclavable	20-475
D300 100 076	03701217803244	Laryngoscope 10.0 mm autoclavable 70°	Laryngoscope 10mm 70° 159mm autoclavable	20-475
D300 100 077	03701217803237	Laryngoscope 10.0 mm autoclavable 90°	Laryngoscope 10mm 90° 159mm autoclavable	20-475
D300 100 078	03701217803220	Otoscope 1.9 mm autoclavable 0°	Otoscope 1,9mm 0° 100mm autoclavable	20-475
D300 100 079	03701217803213	Otoscope 1.9 mm autoclavable 30°	Otoscope 1,9mm 30° 100mm autoclavable	20-475
D300 100 080	03701217803206	Otoscope 2.7 mm autoclavable 0°	Otoscope 2,7mm 0° 75mm autoclavable	20-475
D300 100 081	03701217803190	Otoscope 2.7 mm autoclavable 30°	Otoscope 2,7mm 30° 75mm autoclavable	20-475
D300 100 082	03701217803183	Otoscope 2.7 mm autoclavable 70°	Otoscope 2,7mm 70° 75mm autoclavable	20-475
D300 100 083	03701217803176	Otoscope 4.0 mm non-autoclavable 0°	Otoscope 4mm 0° 50mm non-autoclavable	20-475
D300 100 084	03701217803169	Otoscope 4.0 mm non-autoclavable 30°	Otoscope 4mm 30° 50mm non-autoclavable	20-475
D300 100 085	03701217803152	Arthroscope 1.9 mm autoclavable 0°	Arthroscope 1,9mm 0° 60mm autoclavable	20-475
D300 100 086	03701217803145	Arthroscope 1.9 mm autoclavable 30°	Arthroscope 1,9mm 30° 60mm autoclavable	20-475
D300 100 087	03701217806474	HD 2,9mm Bariatric hysteroscope, 12°, 395mm autoclavable	Hystéroscope bariatrique HD 2,9mm, 12°, 395mm autoclavable	20-475
D300 100 088	03701217806535	HD 2,9mm Bariatric hysteroscope, 30°, 395mm autoclavable	Hystéroscope bariatrique HD 2,9mm, 30°, 395mm autoclavable	20-475
D300 100 090	03701217808690	HD hysteroscope 2mm 30° 260mm autoclavable	HD hysteroscope 2mm 30° 260mm autoclavable	20-475