

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:

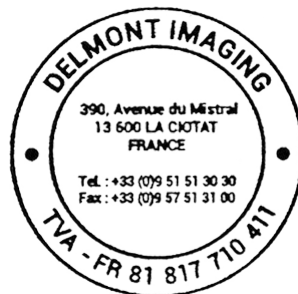
Generic name: Minimally invasive HF instrument
Risk classification: IIb, rule 9
Basic UDI-DI: 37012178HFINGZ

Based on the following elements:

Conformity route: Annex II point 3 Directive 93/42/CEE
Technical file: TF- HFIN
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: 2024-09-03



Applicable standards

EN ISO 10993-18:2020/A1:2023; EN ISO 14971:2019/A11:2021; EN ISO 13485:2016/AC:2018/A11:2021; EN 62366-1:2015/A1:2020; EN 60601-1-6:2010/A1:2015/A2:2021; EN 60601-1:2006/A1:2014/A12:2016/A2:2021; EN ISO 10993-2:2022; XP ISO/TS 10993-19:2022; EN ISO 10993-23:2021; EN ISO 10993-12:2021; EN ISO 17664-1:2021; EN ISO 15223-1:2021; EN ISO 20417:2021; EN ISO 10993-1:2020; EN ISO 11138-7:2019; ISO/TS 21726:2019; EN IEC 60601-2-2:2018; EN ISO 10993-11:2018; EN ISO 80369-1:2018; EN ISO 10993-16:2017; EN ISO 7153-1:2016; EN ISO 10993-10:2013; EN ISO 10993-13:2010; EN ISO 10993-5:2010; EN ISO 10993-17:2009; EN ISO 17665-1:2006;

REF	GTIN/UDI-DI	Description EN
D300 120 502	03701217805217	Monopolar metal handle, rotative and no ratchet for 3mm instru
D300 120 503	03701217805200	Monopolar plastic handle, rotative and stepless ratchet for 3mm instru
D300 120 504	03701217805194	Monopolar plastic handle, rotative, without ratchet for 3mm instru
D300 120 505	03701217805187	Monopolar plastic handle, rotative, with ratchet for 3mm instru
D300 120 506	03701217805170	3mm straight scissors, Metzenbaum type, double action jaws
D300 120 507	03701217805163	3mm curved scissors, Metzenbaum type, double action jaws
D300 120 508	03701217805156	3mm hook scissors, single action jaws
D300 120 509	03701217805149	3mm straight micro-scissors, single action jaws
D300 120 510	03701217805132	3mm universal grasping forceps, wavy and toothed, double action jaws
D300 120 511	03701217805125	3mm Maryland grasping forceps, double action jaws
D300 120 512	03701217805118	3mm dissecting forceps, fenestred, double action jaws
D300 120 513	03701217805101	3mm dolphin grasping forceps, double action jaws
D300 120 514	03701217805095	3mm sharp grasping forceps, with crosswise teeth, double action jaws
D300 120 515	03701217805088	3mm claw grasping-extracting forceps, 2x3 teeth, single action jaws
D300 120 516	03701217805071	3mm biopsy forceps, double action jaws
D300 120 520	03701217805064	3mm blunt grasping forceps with reservoir, double action jaws
D300 120 600	03701217805057	5mm grasping and extracting forceps, 2x3 teeth, single action jaws
D300 120 601	03701217805040	5mm Maryland dissecting forceps, double action jaws
D300 120 602	03701217805033	5mm fallopian tube grasping forceps, double action jaws
D300 120 603	03701217805026	5mm Mixer clamp, 90°, double action jaws
D300 120 604	03701217805019	5mm straight scissors, Metzenbaum type, double action jaws
D300 120 605	03701217805002	5mm hook scissors, single action jaws
D300 120 629	03701217804999	5mm tenaculum grasping forceps, double action jaws
D300 120 630	03701217804982	5mm atraumatic DeBakey grasping forceps, 30mm jaws, double action jaws
D300 120 631	03701217804975	5mm atraumatic DeBakey grasping forceps, 45mm jaws, double action jaws
D300 120 632	03701217804968	5mm atraumatic organ grasping forceps, double action jaws
D300 120 633	03701217804951	5mm Cobra grasping forceps with 2x4 teeth, double action jaws
D300 120 634	03701217804944	5mm grasping forceps, fenestrated, double action jaws
D300 120 635	03701217804937	5mm grasping forceps, spoon-shaped, single action jaws
D300 120 636	03701217804920	5mm long grasping forceps, fenestrated, single action jaws

REF	GTIN/UDI-DI	Description EN
D300 120 637	03701217804913	5mm Babcock clamp, single action jaws
D300 120 638	03701217804906	5mm Duck-Bill grasping forceps, double action jaws
D300 120 639	03701217804890	5mm Dolphin grasping forceps with reservoir, double action jaws
D300 120 640	03701217804883	5mm Vario grasping forceps, double action jaws
D300 120 641	03701217804876	5mm DeBaKey grasping forceps, single action jaws
D300 120 642	03701217804869	5mm atraumatic grasping forceps with reservoir, single action jaws
D300 120 643	03701217804852	5mm biopsy forceps, double action jaws
D300 120 644	03701217804845	5mm biopsy forceps with double thorn, double action jaws
D300 120 645	03701217804838	5mm Peritoneal straight scissors, single action jaws
D300 120 646	03701217804821	5mm curved scissors, Metzenbaum type, double action jaws
D300 120 647	03701217804814	5mm curved mini-scissors, Metzenbaum type, double action jaws
D300 120 648	03701217804807	5mm straight micro-scissors, single action jaws
D300 120 649	03701217805453	Ø 5mm L-Hook monopolar electrode, working length: 350mm
D300 120 650	03701217806139	Ø 5mm Button monopolar electrode, working length: 350mm
D300 120 651	03701217806146	Ø 5mm J-Hook monopolar electrode, working length: 350mm
D300 120 652	03701217806153	Ø 5mm Spatula monopolar electrode, working length: 350mm
D300 120 653	03701217806160	Ø 2,7mm L-Hook monopolar electrode, working length: 350mm
D300 120 700	03701217804791	10mm grasping and extracting forceps, 2x3teeth, single action jaws
D300 120 701	03701217804784	10mm biopsy forceps, large cup, single action jaws
D300 120 702	03701217804777	5mm atraumatic dissecting and grasping forceps, double action jaws
D300 120 703	03701217804760	5mm Vario grasping forceps, long version, double action jaws
D300 120 704	03701217804753	5mm atraumatic grasping forceps, fenestrated, double action jaws
D300 120 705	03701217804746	5mm Kelly grasping and dissecting forceps, double action jaws
D300 120 706	03701217804739	10mm Babcock grasping forceps, double action jaws
D300 120 707	03701217804722	10mm Maryland grasping forceps, double action jaws
D300 120 708	03701217804715	10mm grasping forceps, spoon-shaped, double action jaws
D300 120 709	03701217804708	10mm Mixer clamp, 90°, double action jaws
D300 120 710	03701217804692	10mm tip holding forceps, double action jaws
D300 120 711	03701217804685	10mm Babcock clamp with plateau, double action jaws
D300 120 750	03701217804678	5mm bipolar grasping forceps, fenestrated, double action jaws
D300 120 751	03701217804661	5mm bipolar slim forceps, curved, double action jaws
D300 120 752	03701217804654	5mm bipolar grasping forceps, curved, fenestrated, double action jaws
D300 120 753	03701217804647	5mm curved bipolar scissors, metzenbaum type, double action jaws
D300 120 754	03701217804630	5mm dissection Maryland bipolar forceps, curved, double action jaws
D300 120 755	03701217804623	5mm grasping bipolar forceps w/ teeth, fenestrated, double action jaws
D300 120 756	03701217804616	Bipolar handle for 5mm instruments
D300 120 757	03701217804609	5mm insulated shaft, working length 340mm with rotation module

REF	GTIN/UDI-DI	Description EN
D300 120 758	03701217804593	Bipolar handle for 3mm instruments
D300 120 759	03701217804586	3mm insulated shaft, working length 290mm with rotation module
D300 120 760	03701217804579	3mm bipolar grasping forceps, fenestrated, double action jaws, L:290mm
D300 120 761	03701217804562	3mm dissection Maryland bipolar forceps, curved, double action jaws, L:290mm
D300 120 762	03701217805446	Ø 3mm L-Hook bipolar electrode, working length: 340mm
D300 120 763	03701217805439	Ø 3mm straight bipolar electrode, working length: 340mm
D300 120 764	03701217805422	Ø 3mm V-Hook bipolar electrode, working length: 340mm
D300 120 765	03701217806177	Ø 5mm L-Hook bipolar electrode, working length: 340 mm
D300 120 766	03701217806184	Ø 5mm Spatula bipolar electrode, working length: 340mm
D300 120 767	03701217806207	Ø 5mm Button bipolar electrode, working length: 340mm
D300 120 768	03701217804555	5mm claw bipolar grasping forceps, fenestrated, double action jaws
D300 120 769	03701217804548	5mm Duck Bill bipolar grasping forceps, fenestrated double action jaws
D300 120 770	03701217804531	5mm Delta bipolar grasping forceps, fenestrated, double action jaws
D300 120 771	03701217806214	Ø 5mm J-Hook bipolar electrode, working length: 340 mm
D300 120 772	03701217805415	Ø 3mm L-Hook bipolar electrode, working length: 360mm
D300 120 773	03701217805408	Ø 3mm straight bipolar electrode, working length: 360mm
D300 120 774	03701217805392	Ø 3mm V-Hook bipolar electrode, working length: 360mm
D300 120 775	03701217806252	3mm insulated shaft, working length 350mm with rotation module
D300 120 776	03701217806269	3mm bipolar grasping forceps, fenestrated, double action jaws, L:350mm
D300 120 777	03701217806276	3mm dissection Maryland bipolar forceps, curved, double action jaws, L:350mm
D300 120 778	03701217806429	3mm curved bipolar scissors, metzenbaum type, double action jaws, L:290mm
D300 120 779	03701217806436	3mm curved bipolar scissors, metzenbaum type, double action jaws, L:350mm
D300 120 800	03701217804524	Monopolar metal handle, rotative without ratchet, for 10mm instru
D300 120 801	03701217804517	Monopolar plastic handle, rotative without ratchet, for 10mm instru
D300 120 802	03701217804500	Monopolar metal handle, rotative with ratchet, for 10mm instru
D300 120 803	03701217804494	Monopolar plastic handle, rotative with ratchet, for 10mm instru
D300 120 804	03701217804487	5mm insulated shaft, working length: 350mm
D300 120 805	03701217804470	10mm insulated shaft, working length: 350mm
D300 120 813	03701217806191	Ø 5mm L-Hook monopolar electrode, working length: 350mm, with suction
D300 120 814	03701217806221	Ø 5mm Button monopolar electrode, working length: 350mm, with suction
D300 120 815	03701217806238	Ø 5mm Spatula monopolar electrode, working length: 350mm, with suction
D300 120 816	03701217806245	Ø 5mm J-Hook monopolar electrode, working length: 350mm, with suction
D300 120 865	03701217806627	Ø5mm insulated shaft, WL:330mm, with Luer-lock connection
D300 140 010	03701217802230	Bipolar electrode, flexible, button type, 5Fr.
D300 140 011	03701217802247	Bipolar electrode, flexible, needle type, 5Fr.
D300 140 038	03701217802513	Bipolar electrode, flexible, curved needle type, 5Fr.
D300 140 133	03701217803732	Bipolar L-hook electrode, 3mm, rigid, WL 345mm

REF	GTIN/UDI-DI	Description EN
D300 140 134	03701217803749	Bipolar ball electrode, 3mm, rigid, WL 345mm
D300 140 135	03701217803756	Bipolar V-shape electrode, 3mm, rigid, WL 345mm