



EU Declaration of Conformity

According to Annex IV of the Regulation (EU) 2017/745 concerning medical devices, we:

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

Manufacturing site: Delmont imaging, 297 avenue du Mistral, 13600 La Ciotat, France

Declare under our responsibility (see list in annex for details and accessories):

Generic name: Endoscopic image processing and light source system
Risk classification: I, rule 10
Basic UDI-DI: 37012178ICARG9

Based on the following elements:

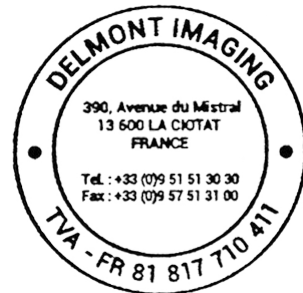
Conformity route: Annex II and III the European Regulation (EU) RG 2017/745
Technical file: TF-ICAR

We certify and declare that the medical device specified above complies with the requirements of:

- the European Regulation (EU) RG 2017/745, of the European Parliament and of the Council of 5 April 2017 on medical devices,
- the European Directive (EU) DI 2011/65/EC (RoHS) of the European Parliament and of the Council of 2 January 2013, dealing with restrictions on the use of certain hazardous substances in electrical and electronic equipment,
- the European Directive (EU) DI 2006/42/CE of the European Parliament and of the Council of 17 May 2006 on machinery,
- the European Directive (EU) DI 2011/65/EC (RED) of 16 April 2014 of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment.

Name: MONTILLOT Pierre
Function: CEO
Revision date: 2024-08-26
Date of validity: 2029-08-25

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



Applicable standards

EN 60601-1:2006/A1:2014/; EN 60601-1-2:2015; EN 60601-1-6:2010/A1:2015; EN 60601-2-18:2016; EN 62304:2006/A1:2018; EN 62366-1:2015/A1:2020; EN 62471:2008; EN IEC 80001-1:2021; EN ISO 10993-1:2020; EN ISO 10993-12:2021; EN ISO 10993-18:2020; EN ISO 12052:2017; EN ISO 13485:2016/A11:2021; EN ISO 14971:2019; EN ISO 15223-1:2021; EN ISO 17664-2:2021; EN ISO 20417:2021; EN ISO/IEC 27001:2017; FD CEN ISO/TR 24971:2020; IEC/TR 80002-1:2009; IEC/TR 80002-3:2014; ISO 12233:2017; ISO 15223-2:2010; ISO 16142-1:2016.

REFERENCE	UDI-DI	DECSRIPTION
D100 100 000	03701217808508	iCare SLIDE. Camera control unit only
D100 100 001	03701217803008	iCare without SLIDE. Camera control unit only
D100 100 020	03701217807167	iSee. Camera control unit only
D100 100 040	03701217807174	iLight. LED light source
D100 110 000	03701217808577	iCare camera head only. Without coupler.
D100 120 000	03701217808584	Coupler of focal lenght f=22mm
D100 120 001	03701217800038	Coupler of focal lenght f=18mm
D100 120 002	03701217800045	Zoom coupler of focal lenght f=16 to 34mm
D100 200 106	03701217806047	imagyn license, Hysteroscopy, with data backup function
D100 200 107	03701217806030	imagyn sub-license with data backup function
D100 200 108	03701217806023	imagyn license, Hysteroscopy, without data backup function
D100 200 109	03701217806016	MyReport license with data backup function
D100 200 110	03701217806009	MyReport sub-license with data backup function
D100 200 111	03701217805996	MyReport license without data backup function
D100 200 112	03701217807884	imagyn license, Colposcopy, with data backup function
D100 200 113	03701217806818	imagyn license Premium, Hysteroscopy and Colposcopy, with data backup function
D100 200 114	03701217807877	imagyn license, Colposcopy, without data backup function
D100 200 115	03701217807860	imagyn license Premium, Hysteroscopy and Colposcopy, without data backup function
D100 200 116	03701217806825	Activation of all imagyn specialities
D100 200 117	03701217803664	imagyn license Premium, Hysteroscopy and Colposcopy, with interoperability
D100 200 118	03701217803657	imagyn license, Hysteroscopy, with interoperability
D100 200 119	03701217803640	imagyn license, Colposcopy, with interoperability
D100 200 120	03701217803633	MyReport license with interoperability
D100 200 123	03701217805521	Activation of interoperability feature
D100 200 124	03701217805538	Activation of local data backup (NAS kit + License)
D200 150 000	03701217800052	Light cable, grey, Ø: 3,5mm, L: 2,3m
D200 150 001	03701217800069	Connector Storz for light cable endoscope side
D200 150 002	03701217800076	Connector Storz for light cable light source side
D200 150 003	03701217800083	Connector Olympus for light cable light source side
D200 150 004	03701217802841	Connector ACMI / Stryker for light cable light source side
D200 150 005	03701217803084	Light cable, grey, Ø: 4,8mm, L: 2,3m
D200 150 008	03701217802612	Connector Richard Wolf for light cable light source side
D200 150 500	03701217800090	Light cable, grey, Ø: 3,5mm, L: 2,3m with Storz connectors
D200 150 501	03701217804050	Light cable, grey, Ø: 4,8mm, L: 2,3m with Storz connectors