



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

Declare under our responsibility the medical device (see list below for details and accessories):

Generic name: Colposcope system
Risk classification: I, rule 10
Basic UDI-DI: 37012178COLPHQ

Based on the following elements:

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

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

- the European Regulation (EU) RG 2017/745 (MDR), 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.

Representative name: MONTILLOT Pierre
Representative function: CEO
Revision date: 2024-07-01
Date of validity: 2029-06-30

A handwritten signature in black ink, appearing to be 'P. Montillot', is written over a light gray diagonal band.



APPLICABLE STANDARDS

EN 60601-1:2006/A1:2014/A12:2016/A2:2021; EN 60601-1-2:2016/A1:2021; EN 60601-1-6:2010/A1:2015/A2:2021; ISO 10935:2009; EN 62366-1:2015/A1 :2020; EN ISO 13485:2016/AC:2018/A11:2021; EN 14971:2019/A11:2021; EN ISO 15223-1:2021; EN ISO 17664-2:2021; EN ISO 20417:2021; EN 62304:2006/A1:2018; IEC 62471:2008; EN ISO 10993-1:2020

REF	UDI-DI	DESCRIPTION EN
D100 300 000	03701217807815	LED Colposcope swing arm, 5-steps magnification, 45° eyepiece
D100 300 001	03701217807808	LED Colposcope over the shoulder, 5-steps magnification, 45° eyepiece
D100 300 002	03701217807792	LED Colposcope vertical stand, 3-steps magnification, 45° eyepiece
D100 300 003	03701217807785	Beamsplitter dual port - 50/50 & 20/80
D100 300 004	03701217807778	Objective with variable focal between 200mm and 350mm
D100 300 005	03701217807761	Video camera adapter
D100 300 006	03701217807754	C-mount to endoscope eye-piece adapter
D100 300 008	03701217807730	Arm For Colp/Schmitz Chair
D100 300 009	03701217807723	Colposcope to Sony Camera/Video Adapter
D100 300 014	03701217807679	Laser protection filter 780nm -2940nm
D100 300 015	03701217807662	Colposcope LED light source
D100 300 019	03701217807655	Laser protection filter 9000nm -11000nm
D100 300 020	03701217807648	Colposcope objective lens F=175mm
D100 300 021	03701217807631	Colposcope objective lens F=200mm
D100 300 022	03701217807624	Colposcope objective lens F=250mm
D100 300 023	03701217807617	Colposcope objective lens F=300mm
D100 300 024	03701217807600	Colposcope objective lens F=400mm
D100 300 027	03701217807570	Liquid light guide 80cm for colposcope
D100 300 028	03701217807563	Liquid light guide 130cm for colposcope
D100 300 029	03701217807556	Liquid light guide 150cm for colposcope
D100 300 030	03701217807549	Liquid light guide 175cm for colposcope
D100 300 061	03701217805910	Monitor stand for over-the-shoulder or swing arm colposcope
D100 300 550	03701217803060	iCare mini. HD Colposcopy camera, CS-mount

COMMERCIAL SETS

REF	DESCRIPTION EN	CONTENTS
D100 300 500	Straight LED colposcope, 3 magnifications, 45° binocular, 300mm objective	D100 300 002 + D100 300 023
D100 300 501	Straight LED colposcope, 3 magnifications, 45° binocular, Variofocus objective	D100 300 002 + D100 300 004
D100 300 502	Swing arm LED colposcope, 5 magnifications, 45° binocular, 300mm objective	D100 300 000 + D100 300 023
D100 300 503	Swing arm LED colposcope, 5 magnifications, 45° binocular, Variofocus objective	D100 300 000 + D100 300 004
D100 300 506	Over-the-shoulder LED colposcope LED, 5 magnifications, 45° binocular, 300mm objective	D100 300 001 + D100 300 023
D100 300 507	Over-the-shoulder LED colposcope LED, 5 magnifications, 45° binocular, Variofocus objective	D100 300 001 + D100 300 004
D100 300 510	Complete kit for video camera	D100 300 003 + D100 300 005 + D100 300 006