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 sole responsibility the medical device (see below for details and accessories):

Generic name:	Irrigation fluid management system
Basic UDI-DI:	37012178IFLMHF
Risk classification:	IIb, rule 12

Based on the following elements:

Conformity route:	Annex IX of the European Regulation (EU) RG 2017/745
Technical file:	TF- IFLM
Notified body:	SIQ (1304), Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia
EC certificate:	MDR-0021
Valid until:	2029-11-07

We certify and declare that the medical device specified above 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 2012/19/CE of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).
- The European Regulation (EU) RG 2021/2226, of the European Parliament and of the Council of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 as regards electronic instructions for use of medical devices.

Representative name:	MONTILLOT Pierre
Representative function:	CEO
Revision date:	2024-11-08
Date of validity:	2029-11-07

Applicable standards
EN 556-1:2002; 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; EN 60601-1-8:2007+A11:2018+A2:2021; EN 62304:2006+A1:2018; EN 62366-1:2015+A1:2020; EN 80369-5:2017; EN ISO 10993-1:2020; EN ISO 10993-2:2022; EN ISO 10993-5:2010; EN ISO 10993-7:2008+A1:2022; EN ISO 10993-10:2023; EN ISO 10993-11:2018; EN ISO 10993-18:2020; EN ISO 10993-23:2021; EN ISO 11737-2:2020; EN ISO 13485:2016+AC:2018+A11:2021; EN ISO 14971:2019+A11:2021; EN ISO 15223-1:2021; EN ISO 17664-2:2021; EN ISO 20417:2021; EN ISO 80369-1:2018; EN ISO 8536-4:2020; EN ISO 8536-9:2015; EN ISO 11135: 2014+A1:2019; EN ISO 11607-1:2020; EN ISO 11607-2:2020;

REF	UDI-DI	Description
D110 100 012	03701217808713	iFlow mini. Irrigation pump. Hysteroscopy and Laparoscopy
D110 100 013	03701217808720	3 liters pressure cuff for iFlow mini, long version
D110 100 014	03701217808737	1 liter pressure cuff for iFlow mini
D110 100 015	03701217808645	Sterile. Single-use irrigation tube. 1 spike.
D110 100 016	03701217808669	Sterile. Single-use irrigation tube. 2 spikes.
D110 100 017	03701217808621	Vacuum suction tube with filter, non-sterile, for 30 days of use
D110 100 018	03701217801295	Y-adapter for double pressure cuff connection
D110 100 019	03701217805569	Self-test tube for iFlow mini pressure sensor
D110 100 020	03701217802698	3 liters pressure cuff for iFlow mini
D110 100 022	03701217805903	Sterile. Single-use suction tube. 2 connectors.

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