Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates), and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

Manufacturer name	Delmont imaging
Manufacturer address and contact details	390 avenue du Mistral, 13600 La Ciotat, France
Single Registration Number (SRN) (if available)	FR-MF-000000157
Notified body name	SIQ
Notified body number	1304
Directive Certificate number	MDD-085
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-27
End date of extended validity/transition period	2028-12-31

We, as the manufacturer declare under our sole responsibility:

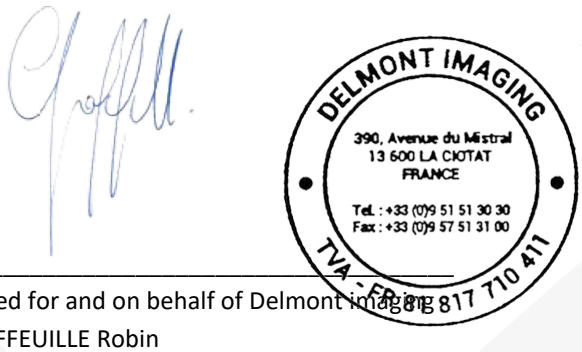
- for the above listed **Directive Certificate,** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met, and
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate** as listed above:
  - Was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards, and
  - Expire after the 20 March 2023, and
  - Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreement(s) is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- Quality Management System (QMS), in accordance with Article 10(9) MDR, is in place.

- Devices as listed in the attached schedule continue to comply with the MDD:
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.



La Ciotat, the 04tf of July 2024,

Signed for and on behalf of Delmont imaging
GREFFEUILLE Robin
Quality and regulatory manager

The manufacturer's Declaration is valid for the following devices:

Identification of the devices	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity transition period
Endoscopes	MDD-085	2024-05-27	SIQ (1304)	SIQ (1304)	2028-12-31
Resectoscopy system	MDD-085	2024-05-27	SIQ (1304)	SIQ (1304)	2028-12-31
Hysteroscopy system	MDD-085	2024-05-27	SIQ (1304)	SIQ (1304)	2028-12-31
HF-electrodes	MDD-085	2024-05-27	SIQ (1304)	SIQ (1304)	2028-12-31
HF Instruments	MDD-085	2024-05-27	SIQ (1304)	SIQ (1304)	2028-12-31
Uterine Manipulator – resuable	MDD-085	2024-05-27	SIQ (1304)	SIQ (1304)	2028-12-31