EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III

Certificate No. MDR-0021

Issued to:	DELMONT IMAGING 390 Avenue du Mistral, La Ciotat 13600 France
SRN of the manufacturer:	FR-MF-000000157
EU authorised representative:	Not applicable
SRN of EU authorised representative:	Not applicable

SIQ has audited the quality management system in accordance with MDR Annex IX and found that the above-mentioned Manufacturer's quality management system meets the requirements of the Regulation (EU) 2017/745 concerning medical devices Annex IX. Devices covered by the Manufacturer's quality management system are listed on the page(s) below.
This certificate is based on

Audit reports No.:
OSV 01721/2023, 2024-01-31
OSV 00994/2024, 2024-07-12
OSV 01184A/2024, 2024-10-21.

See also decision of NB`s commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality management system is subject to periodical surveillance as referred to in Regulation (EU) 2017/745 concerning medical devices Annex IX and continues to meet the above requirements.

Reference to any previous certificate: /

Certification date:	2024-11-08
Issue:	01/2024-11-08
Valid until:	2029-11-07

Managing Director of SIQ
Gregor Schoss

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Device:	Various instruments for general and multidisciplinary surgery
EMDN:	Z120190
Intended purpose:	The irrigation fluid management system is a non-invasive, active medical device intended for fluid management in endoscopic settings to provide distension, fluid irrigation and suction function.
Classification:	IIb
Specific conditions for or provisions or limitations to the validity of certificate:	/

Certification date:	2024-11-08
Issue:	01/2024-11-08
Valid until:	2029-11-07

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