EC Certificate – Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate No. MDD-085

Issued to:	DELMONT IMAGING
	390 Avenue du Mistral, La Ciotat 13600, FRANCE
Place of production:	Different OEM
Product category:	Endoscopes
UMDNS:	20-475
Product category:	Resectoscopy System
GMDN:	35301, 61872, 61873, 62061
Product category:	Hysteroscopy System
GMDN:	37086
Product category:	HF-electrodes
GMDN:	61873, 62061
Product category:	HF Instruments
GMDN:	61873, 62061
Product category:	Uterine Manipulator - reusable
GMDN:	63994

SIQ has audited the quality system in accordance with MDD Annex II excluding (4) and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex II. This certificate is based on

Audit report No.:
OSV 00811/2019, 2019-06-28
OSV 01240/2019, 2020-02-25
OSV 01240A/2019, 2020-02-28
OSV 00150/2020, 2020-04-28
OSV 00603/2020, 2020-08-27

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

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex II (5) and continues to meet the above requirements.

Certification date: 2018-01-16

Issue: 6/2020-08-31

Valid until: 2024-05-27

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Director of SIQ
Igor Likar