



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

Product category: Rigid medical endoscopes
GMDN: 20-475

Product category: Electrode for HF resection
GMDN: 42553

Product category: Resectoscopy System
GMDN: 37085 and 37086

Product category: Hysteroscopy System
GMDN: 37086

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 00995/2017, 2017-10-24
OSV 01116/2017, 2017-11-24
OSV 01107/2017, 2017-12-22
OSV 01256/2017, 2017-12-27
OSV 01380/2017, 2017-12-29
OSV 00001A/2018, 2018-1-16

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: 2/2018-07-03

Valid until: 2021-01-16



Director of SIQ

Igor Likar