



**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  
163 Avenue de Luminy, Batiment CCIMP case 943, Marseille, 13009,  
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

**SAO Y BAN CHINH**  
Ngày 14 tháng 6 năm 2018



**GIÁM ĐỐC**

*Mason*

*Khong Mai Anh*

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: 1/2018-01-16

Valid until: 2021-01-16



Director of SIQ

*Igor Likar*