



Health Technology Certification

# EC-CERTIFICATE

## FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

### ISOMed S.a.r.l.

ZAE Les Pointes 230, rue des Grands Prés  
Chambly, 60230  
France

for design and manufacture of

**Huber needles, Balloon catheters,  
Venous introducers, Venous strippers.**

*Further details are given overleaf*

fulfills the requirements of Annex II excluding (4) of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate No: 2204C04210402  
Issue Date: 02/04/2021  
Original Approval: 17/02/2021  
Valid until: 26/05/2024  
References: W001 2204 01

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number 2803

For and on behalf of HTCert Ltd

GEORGE PAPPOUS  
Managing Director

FILIPPOS KOTTIS  
Certification Director

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