EC CERTIFICATE

Number: 2107231CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Lifetech Scientific (Shenzhen) Co., Ltd.

Floor 1-5 Cybio Electronic Building
Langshan 2nd Street
North Area of High-tech Park
Nanshan District
518057 Shenzhen
China

For the product category(ies)

Endovascular, cardiovascular implants, delivery and retrieval systems and accessories

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:
Certification Notice 2107231CN, initially dated 26 September 2008
Addendum, initially dated 18 May 2009

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 October 2022
Issued for the first time: 26 September 2008
Reissued: 12 October 2017

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2107231CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Endovascular, cardiovascular implants, delivery and retrieval systems and accessories

Issued to:

Lifetech Scientific (Shenzhen) Co., Ltd.
Floor 1-5 Cybio Electronic Building
Langshan 2nd Street
North Area of High-tech Park
Nanshan District
518057 Shenzhen
China

This certificate covers the following product(s):

- Vena Cava Filter: Aegisy filter and delivery system (Class III)
- Cera Closure System: Cera Occluders and delivery system (Class III)
- CeraFlex Closure System: CeraFlex Occluders and delivery system (Class III)
- HeartR Closure System: HeartR Occluders and delivery system (Class III)
- Cera Vascular Plug and Delivery system (Class III)
- CeraFlex Vascular Plug and Delivery System (Class III)
- FuStar Steerable Introducer (Class IIa)
- SeQure Snare System (Class IIa)
- AcuMark Sizing Balloon (Class III)
- Ankura Stent Graft System for endovascular repair of patients with aortic and aorta-iliac aneurysms:
- Ankura stent graft and associated delivery system (Class III)
- Surpass Super stiff Guidewire (Class IIa)
- SteerEase™ Introducer (Class IIa)
- IrisFIT PFO Closure System: IrisFIT PFO Occluders and delivery systems (Class III)
- LawMax Dilator (Class IIa)
- KONAR-MF VSD Occluder (Class III)

Initial date: 18 May 2009
Revision date: 16 March 2018

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drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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