DEKRA Certification B.V.

Notification on Approval

Date: December 15, 2021

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
P.R. of China

8 F, Lifetech Scientific Building No. 22
Keji 12th Road South
High-Tech Industrial Park
Yuehai Subdistrict
Nanshan District
518063 Shenzhen
P.R. of China

To Whom It May Concern,

DEKRA Certification, in its capacity of Notified Body for Medical Devices, declares, based on the results of the assessment activities performed, that approval of the proposed change NoC 2021-09 is granted, as is recommended in report 2260206-RL01-R1.

2196:3

The change describes the address change for company's medical device business from:
Floor 1-5 Cybio Electronic Building
Langshan 2nd Street
North Area of High-tech Park
Nanshan District
518057 Shenzhen
P.R. of China

to the new address:
8 F, Lifetech Scientific Building No. 22
Keji 12th Road South
High-Tech Industrial Park
Yuehai Subdistrict
Nanshan District
518063 Shenzhen
P.R. of China

The existing certificates are affected:

- 2107230 (ISO 13485:2016 certification);
- 2107231CE01, -DE01, -DE02, -DE03, -DE04, -DE05, -DE06 and -DE07.

Change NoC 2021-09 is considered a non-significant change in design or intended purpose under MDR article 120(3). The related MDD certificate(s) remain valid until its expiry date or 26 May 2024, whichever comes first.

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J.A. van Vugt
Principal Certification Manager Medical Devices

Lifetech Scientific (Shenzhen) Co., Ltd.
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Nanshan District
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SRN ID.: CN-MF-000001561

Your ref.
Our ref. MED/23-147
Tel. +31 88 96 83 009
Fax +31 88 96 83 100
E-mail medical.nl@dekra.com

Arnhem, 1 June 2023

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Lifetech Scientific (Shenzhen) Co., Ltd.
8 F, Lifetech Scientific Building, No. 22
Keji 12th Road South, High-Tech Industrial Park
Yuehai Subdistrict, Nanshan District
518063 Shenzhen
P.R. of China

SRN ID.: CN-MF-000001561

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

A.J. Knipmeijer
Project Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Cardiovascular Closure Systems to treat defects in the heart: **Cera, Cera Flex Occluders, IrisFIT PFO Occluders, HeartR Occluders, and delivery systems** - Cera PDA Closure System - Cera VSD Closure System - Cera PFO Closure System - CeraFlex PDA Closure System - CeraFlex PFO Closure System - HeartR VSD Closure System - HeartR PDA Closure System	Class III	N/A	2107231DE02; NB 0344
KONAR-MF VSD Occluder and delivery system: Cardiovascular Closure Systems to treat defects in the heart Max / Min waist diameter [mm] 5-3, 6-4, 7-5, 8-6, 9-7, 10-8, 12-10, 14-12	Class III	N/A	2107231DE06; NB 0344

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CeraFlex VSD Closure System	Class III	N/A	2107231DE02; NB 0344
IrisFIT PFO Closure System	Class III	N/A	2107231DE02; NB 0344

Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2023/06/01	2107231CN32.1	Initial issue

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
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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: 26 May 2024
Issued for the first time: 26 September 2008
Reissued: 19 February 2021
DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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)
- Futhrough™ Endovascular needle system for intra cavity reconstruction of stent grafts (in-situ) (Class III)
- Xuper Open Surgery Graft System

Initial date: 18 May 2009
Revision date: 20 May 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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