

CERTIFICATE

Number: 2107230

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Lifetech Scientific (Shenzhen) Co., Ltd.

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

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Design, development, production and distribution of endovascular and cardiovascular implants, delivery systems like:

Vena Cava Filters, Occluder / Closure Implants and associated Delivery Systems, Steerable Introducers, Vascular Plug and Delivery Systems, Snare Systems, Sizing Balloons, Stiff Guidewires, Stent Graft Systems and Associated Delivery Systems, Introducer Sheaths, Dilators, Endovascular Needle Systems for Intra Cavity Reconstruction of Stent Grafts, Open Surgery Stent Graft Systems.

Design, development, production and distribution of Lung Volume Reduction Reverser Implantable devices and associated delivery systems.

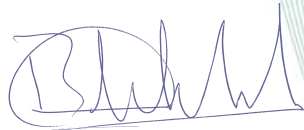
The provision of Ethylene Oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014 and ISO 11135:2014.

Contract Manufacture of Endovascular and Cardiovascular Implantable Devices and associated Delivery Systems.

Certificate expiry date: 1 March 2025
Certificate effective date: 3 March 2022
Certified since: 29 July 2008

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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ADDENDUM

To certificate: 2107230

The management system of the organization(s) and/or location(s) of:

Lifetech Scientific (Shenzhen) Co., Ltd.

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High-tech Industrial Park
Yuehai Subdistrict
Nanshan District
518063 Shenzhen
P.R. China

Certified organization(s) and/or locations:

Different scope

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.China

Design, development, production and distribution of endovascular and cardiovascular implants, delivery systems like: Vena Cava Filters, Occluder / Closure Implants and associated Delivery Systems, Steerable Introducers, Vascular Plug and Delivery Systems, Snare Systems, Sizing Balloons, Stiff Guidewires, Stent Graft Systems and Associated Delivery Systems, Introducer Sheaths, Dilators, Endovascular Needle Systems for Intra Cavity Reconstruction of Stent Grafts, Open Surgery Stent Graft Systems.

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Design of endovascular and cardiovascular implants and associated delivery systems.

Addendum expiry date: 1 March 2025

Addendum effective date: 3 March 2022