

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Thermo Fisher Scientific Baltics
V. A.Graiciuno 8
Vilnius
LT-02241
Lithuania

Holds Certificate No:

FM 642793

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, development, manufacturing and sales of life science research products, including proteins, nucleic acids, nucleotides, antibodies, bio-sample preparation and cell separation reagents and associated kits, for research and in vitro diagnostics..

For and on behalf of BSI:



Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2016-03-25

Latest Revision Date: 2018-05-10

Effective Date: 2018-05-23

Expiry Date: 2021-05-22

Page: 1 of 1



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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Thermo Fisher Scientific Baltics

V. A.Graiciuno 8
Vilnius LT-02241
Lithuania

Holds Certificate Number:

MD 642790

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development and manufacturing of life science products, including proteins, nucleic acids, nucleotides, antibodies and associated kits, for research and in vitro diagnostics, as well as manufacturing of the materials intended for ex-vivo separation of human cells and for cell-based clinical diagnostics and for therapeutic applications, including processes under aseptic conditions.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-02-15

Latest Revision Date: 2018-05-22

Effective Date: 2018-05-23

Expiry Date: 2021-05-22

Page: 1 of 2



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Certificate No: MD 642790

Location

Thermo Fisher Scientific Baltics
V. A.Graiciuno 8
Vilnius
LT-02241
Lithuania

Registered Activities

Design, development and manufacturing of life science products, including proteins, nucleic acids, nucleotides, antibodies and associated kits, for research and in vitro diagnostics, as well as manufacturing of the materials intended for ex-vivo separation of human cells and for cell-based clinical diagnostics and for therapeutic applications, including processes under aseptic conditions.



Original Registration Date: 2016-02-15

Latest Revision Date: 2018-05-22

Effective Date: 2018-05-23

Expiry Date: 2021-05-22

Page: 2 of 2

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Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

MRC Holland BV
Willem Schoutenstraat 1
Amsterdam
1057 DL
The Netherlands

Holds Certificate Number:

MD 716250

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, distribution of in vitro diagnostic medical devices, in vitro diagnostic reagents and in vitro diagnostic software used in genetic testing and tumour DNA/RNA analysis.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-12-19

Latest Revision Date: 2019-12-19

Effective Date: 2019-12-19

Expiry Date: 2022-02-24



Page: 1 of 2

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Certificate No: **MD 716250**

Location

MRC Holland BV
Willem Schoutenstraat 1
Amsterdam
1057 DL
The Netherlands

MRC Holland BV
Willem Schoutenstraat 6
Amsterdam
1057 DN
The Netherlands

Registered Activities

The design, development, manufacture, distribution of in vitro diagnostic medical devices, in vitro diagnostic reagents and in vitro diagnostic software used in genetic testing and tumour DNA/RNA analysis.

The design, development, manufacture of in vitro diagnostic medical devices, in vitro diagnostic reagents and in vitro diagnostic software used in genetic testing and tumour DNA/RNA analysis.



Original Registration Date: 2019-12-19

Latest Revision Date: 2019-12-19

Effective Date: 2019-12-19

Expiry Date: 2022-02-24

Page: 2 of 2

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BSI (UK) Headquarters: Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: 0345 080 9000
A Member of the BSI Group of Companies.



DNV BUSINESS ASSURANCE

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 107563-2011-AQ-RGC-NA

This is to certify that the Management System of:

Thermo Fisher Scientific (Shanghai) Instruments Co., Ltd.

Site 1: T71-6, No. 211, Qin Qiao Road, Jinqiao Export Processing Zone, Pudong, Shanghai 201206, P. R. China

Site 2: No.1028, Jin Min Road, Jinqiao Export Processing Zone, Pudong, Shanghai 201206, P. R. China

Site 3 : Building 3, No. 27, Xin Jinqiao Road, Pudong, Shanghai, P. R. China

Organization Code: 75318619-6

has been found to conform to the standard:

ISO 13485:2003/NS EN-ISO 13485:2012

This Certificate is valid for the following product or service ranges:

Design, Manufacture and Service of Medical Devices Including Tissue Process Equipments for Pathological Analysis, Immunoassay Equipments, Auxiliary Equipments for Lab Test and Biological Safety Cabinets.

Initial Certification date:

20 January 2006

This Certificate is valid until:

20 January 2018

The audit has been performed under the supervision of

Lei Jordan Lu
Lead Auditor



Place and date:

Høvik, 29 January 2015

for the Accredited Unit:
DNV GL Business Assurance
Norway AS.

Eugenie Winger Husebye
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

HEAD OFFICE: Det Norske Veritas AS, Veritasveien 1, 1322 Hovik, Norway. Tel: +47 67 57 99 00 Fax: +47 67 57 99 11 - www.dnv.com

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Life Technologies Corporation
Also Trading As: Invitrogen
3175 Staley Road
Grand Island
New York
14072
USA

Holds Certificate No:

FM 509223

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The design, development, manufacture and distribution of liquid and powder tissue culture media, sera, reagents and distribution of biochemicals.

The above activities are for cell culture research, industrial bioprocessing and related markets.

For and on behalf of BSI:

Reg Blake, VP Regulatory Affairs, BSI Group America Inc.

Original Registration Date: 01/16/2007

Effective Date: 11/06/2015

Expiry Date: 11/05/2018



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Recognized
Registrar



Page: 1 of 2

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Certificate No: **FM 509223**

Location

Life Technologies Corporation
Also Trading As: Invitrogen
3175 Staley Road
Grand Island
New York
14072
USA

Registered Activities

The design, development, manufacture and distribution of liquid and powder tissue culture media, sera, reagents and distribution of biochemicals.

The above activities are for cell culture research, industrial bioprocessing and related markets.

Life Technologies Corporation
Also Trading As: Invitrogen
1775 Baseline Road
Grand Island
New York
14072
USA

Product laboratory testing - Mycoplasma and Sales.



Original Registration Date: 01/16/2007

Effective Date: 11/06/2015

Expiry Date: 11/05/2018

Page: 2 of 2

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To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Life Technologies Ltd.
3 Fountain Drive
Inchinnan Business Park
Paisley
PA4 9RF
United Kingdom

Holds Certificate Number:

MD 507152

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

The design, manufacture and distribution of In-Vitro Diagnostics and products for cell culture, molecular biology and microbiology.

For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 02/10/2006

Latest Revision Date: 24/09/2015

Effective Date: 02/10/2015

Expiry Date: 01/10/2018

Page: 1 of 1



003

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