



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 reagents, proteins, nucleic acids, nucleotides, antibodies, associated kits, and materials intended for ex-vivo separation of human cells for in vitro diagnostics, for further manufacturing and applied market applications, including processes under aseptic condition.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-02-15 Latest Revision Date: 2021-11-17



Effective Date: 2021-05-23 Expiry Date: 2024-05-22

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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 No: MD 642790

Location

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

Thermo Fisher Scientific Baltics Molėtų pl. 5 Vilnius LT-08409 Lithuania **Registered Activities**

Design, development, and manufacturing of reagents, proteins, nucleic acids, nucleotides, antibodies, associated kits, and materials intended for ex-vivo separation of human cells for in vitro diagnostics, for further manufacturing and applied market applications, including processes under aseptic condition.

Manufacturing of nucleotides for in vitro diagnostics and further manufacturing.



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