By Royal Charter

Certificate of Registration

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

This is to certify that:

Elos Medtech AB
Torsgatan 5B
Göteborg,
41104
Sweden

Holds Certificate Number: **MD 680377**

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

Design, Manufacturing, and Sales of general non-active, non-implantable medical devices, non-active implants, dental devices and accessories and components to In Vitro Diagnostic Medical Devices (IVD).

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-12-21
Effective Date: 2018-04-13
Latest Revision Date: 2018-11-22
Expiry Date: 2021-04-11

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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 680377**

Location	Registered Activities
Elos Medtech AB Torsgatan 5B Göteborg, 41104 Sweden	Management responsibility to maintain Elos Medtech's business centers' effectiveness of established quality management systems
Elos Medtech Timmersdala AB Bäckedalsvägen 5 Timmersdala, 540 16 Sweden	Manufacturing of general non-active, non-implantable medical devices, non-active implants, non-active dental devices and accessories
Elos Medtech Pinol A/S Engvej 33 Gørløse 3330 Denmark	Design, Manufacturing and Sales of non-active, non-implantable medical devices, non-active implants, and non-active dental devices.
Elos Medtech Microplast Hästhagsgatan 2, Skara, 532 22 Sweden	Manufacturing of general non-active, non-implantable medical devices, non-active implants, non-active dental devices, and components to In Vitro Diagnostic medical devices (IVD)
Elos Medtech Tianjin D5-3, Rongcheng Sanzhilu, Xeda International Industrial City Xiqing Economic Development Area Tianjin China	Manufacturing of non-active non-implantable diagnostic devices, non-active implants and non-active non-implantable instruments and components.

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