By Royal Charter

Certificate of Registration

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

This is to certify that:

Elos Medtech AB
Nellickevägen 22,
Göteborg,
41263
Sweden

Holds Certificate Number: MD 680377

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

Development, Design, Manufacturing, Packaging and Distribution of general non-active, non-implantable medical devices, non-active implants, non-active 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
Latest Revision Date: 2017-12-21

Effective Date: 2017-12-21
Expiry Date: 2018-04-12

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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.
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Certificate No: MD 680377

Location	Registered Activities
Elos Medtech AB Nellickevägen 22, Göteborg 41263 Sweden	Quality management system – general requirements, management responsibility
Elos Medtech Timmersdala AB Bäckedalsvägen 5 Timmersdala, 540 16 Sweden	Development, Design, Manufacturing, Packaging and Distribution of general non-active, non-implantable medical devices, non-active implants, non-active dental devices and accessories and components to In Vitro Diagnostic Medical Devices (IVD).
Elos Medtech Pinol A/S Engvej 33 Gørløse 3330 Denmark	Development, Design, Manufacturing, Packaging and Distribution of general non-active, non-implantable medical devices, non-active implants, non-active dental devices and accessories and components to In Vitro Diagnostic Medical Devices (IVD).
Elos Medtech Microplast Hästhagsgatan 2, Skara, 532 22 Sweden	Manufacturing and Packaging of general non-active, non-implantable medical devices, non-active implants, non-active dental devices and accessories, and components to In Vitro Diagnostic Medical Devices
Elos Medtech Tianjin D5-3, Rongcheng Sanzhilu, Xeda International Industrial City Xiqing Economic Development Area Tianjin China	Manufacturing and Packaging of general non-active, non-implantable medical devices, non-active implants, non-active dental devices and accessories, and components to In Vitro Diagnostic Medical Devices (IVD).

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