

Certificate of Registration

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

This is to certify that:

Elos Medtech AB
Torsgatan 5B
Göteborg,
411 04
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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-12-21

Latest Revision Date: 2024-03-27

Effective Date: 2024-04-12

Expiry Date: 2027-04-11

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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, 541 71 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 and accessories.
Elos Medtech Skara AB Hästhagsgatan 2, Skara, 532 37 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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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

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

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