

Certificate No.:
244013-2017-AQ-NOR-NA-PS Rev. 0.0

Project No.:
PRJC-437446-2013-MSL-NOR

Initial Certification Date:
27 December 2010

Valid Until:
12 April 2018

This is to certify that the management system of:

Elos Medtech AB

SE-Nellickevägen 22
SE-412 63 Göteborg
SWEDEN

With sites as listed overleaf.

Complies with the requirements of:

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

The Certificate is valid 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, general active medical devices, general active implantable medical devices, and components to In Vitro Diagnostic Medical Devices (IVD).

Place and Date:
Høvik, 21 July 2017



For:
DNV GL NEMKO PRESAFE AS

Bjørg Synnøve Nesgård

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Management System Certificate

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Site Name	Site Address	Site Specific Certificate Scope
Elos Medtech Pinol A/S	Engvej 33, 3330 Gørløse, Denmark	Development, Design, Manufacturing, Packaging and Distribution of general non-active, non-implantable medical devices, non-active implants, non-active dental devices and accessories, general active medical devices, and components to In Vitro Diagnostic Medical Devices (IVD).
Elos Medtech Timmersdala AB	Bäckedalsvägen 5, 540 16 Timmersdala, Sweden	Development, Design, Manufacturing, Packaging and Distribution of general non-active, non-implantable medical devices, non-active implants, non-active dental devices and accessories, general active medical devices, general active implantable medical devices, and components to In Vitro Diagnostic Medical Devices (IVD).
Elos Medtech Microplast AB	Hästhagsgatan 2, 532 22 Skara, Sweden	Manufacturing, 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).
Elos Medtech Tianjin Co. Ltd.	D5-3, Rongcheng Sanzhilu, Xeda International Industrial City, Xiqing Economic Development Area, Tianjin, China.	Manufacturing, 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).

End of Certificate