

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nobel Biocare AB
PO Box 5190, 402 26
Västra Hamngatan 1
Göteborg
411 17
Sweden

Facility ID Number: F000335

Holds Certificate No:

MDSAP 687164

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

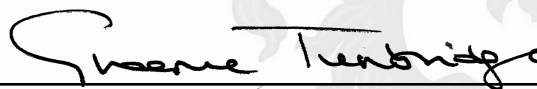
Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-02-12

Effective Date: 2026-10-06

Expiry Date: 2029-10-05



BSI Group America Inc. is an MDSAP recognised auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 687164**

Registered Scope:

The design, manufacture and distribution of oral and extra oral prosthetic reconstruction solutions, endosseous implants, abutments, crowns, bridges, dental kits, other associated dental instruments and accessories and software applications for supporting oral, extraoral and cranio-maxillofacial treatments.

The distribution of biomaterials for dental and other surgical applications.



Original Registration Date: 2019-02-12

Effective Date: 2026-10-06

Expiry Date: 2029-10-05

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 687164**

Location	Registered Activities
Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden Facility ID Number: F000335	Administrative Activities.
Nobel Biocare AB, Produktion Dimbovägen 2 Karlskoga 691 51 Sweden Facility ID Number: F000335	The manufacture of oral and extra oral prosthetic reconstruction solutions, endosseous implants, abutments and other associated dental instruments and accessories.
Nobel Biocare AB, Produktion Verkstadsgatan 1-5 Karlskoga 691 50 Sweden Facility ID Number: F000335	The manufacture of oral and extra oral prosthetic reconstruction solutions, endosseous implants, abutments and other associated dental instruments and accessories.
Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda California 92887 USA Facility ID Number: F001921	The manufacture, of oral and extra oral prosthetic reconstruction solutions, endosseous implants, abutments, dental kits and other associated dental instruments and accessories.
Nobel Biocare Procera, LLC 800 Corporate Drive Mahwah New Jersey 07430 USA Facility ID Number: F001919	The manufacture and distribution of oral prosthetic reconstruction solutions, abutments, crowns and bridges.

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Location	Registered Activities
Nobel Biocare Distribution Center B.V. Popeweg 72 Venlo 5928 SC The Netherlands Facility ID Number: F001918	The relabeling, warehousing and distribution of oral and extra oral prosthetic reconstruction solution, dental kits, endosseous implants, abutments, other associated dental instruments and accessories. The distribution of biomaterials for dental and other surgical applications. Vigilance activities.
Nobel Biocare Services AG Balz-Zimmermann-Strasse 7 Kloten 8302 Switzerland Facility ID Number: F001920	The design, sales, distribution of oral and extra oral prosthetic reconstruction solutions, abutments, crowns and bridges, dental kits, endosseous implants, and other associated dental instruments and accessories. The distribution and sales of software applications for oral, extra oral and cranio maxillofacial surgical solutions. The distribution and sales of biomaterials for dental and other surgical applications. Regulatory Affairs activities.
Nobel Biocare c/o Medicim NV Stationsstraat 102 Mechelen 2800 Belgium Facility ID Number: F001917	The design, manufacture and distribution of software applications for oral, extra oral and cranio-maxillofacial surgical solutions. Regulatory Affairs activities.

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