

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

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 821

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, extra-oral and cranio-maxillofacial treatments. The distribution of biomaterials for dental and other surgical applications.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-02-12

Effective Date: 2021-08-31

Expiry Date: 2023-10-05



BSI Group America Inc. is an MDSAP authorized auditing organization

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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	The sales of oral and extra oral prosthetic reconstruction solutions, dental kits, software applications for oral, extra oral and cranio-maxillofacial surgical solutions, endosseous implants, abutments, crowns, bridges and other associated dental instruments and accessories. The sales of biomaterials for dental and other surgical applications. Legal Manufacturer 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 USA, LLC 22715 Savi Ranch Parkway Yorba Linda California 92887 USA Facility ID Number: F001921	The manufacture, sales, warehousing and distribution of oral and extra oral prosthetic reconstruction solutions, endosseous implants, abutments, dental kits and other associated dental instruments and accessories. The sales and distribution of biomaterials for dental and other surgical applications.
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.
Nobel Biocare Distribution Center B.V. Kozakkenberg 4 Belfeld 5951 DL The Netherlands Facility ID Number: F001918	The manufacture, 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.

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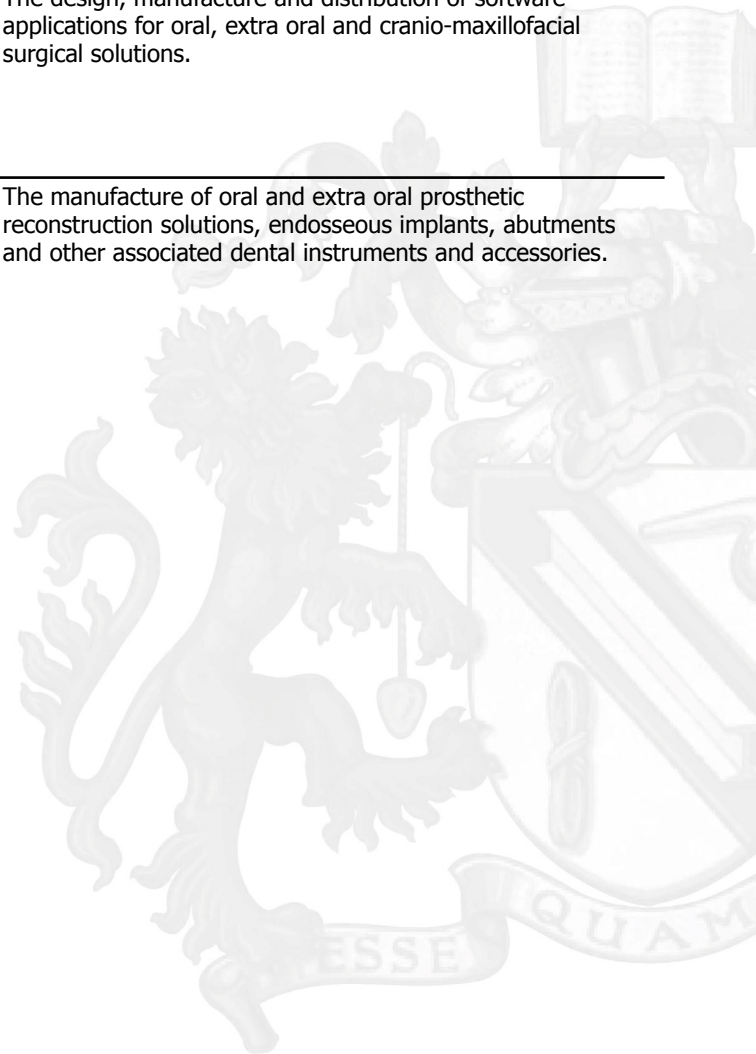
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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

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Location	Registered 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, software applications for oral, extra oral and cranio maxillofacial surgical solution, endosseous implants, and other associated dental instruments and accessories. 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.
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.



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