

Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number:

MD 81731

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, warehousing, sales 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 sales and 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: 2004-03-03

Latest Revision Date: 2021-11-28

Effective Date: 2020-10-06

Expiry Date: 2023-10-05

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Certificate No: **MD 81731**

Location	Registered Activities
Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden	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	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	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	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	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.
Nobel Biocare Services AG Balz-Zimmermann-Strasse 7 Kloten 8302 Switzerland	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

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Location

Nobel Biocare c/o Medicim NV
Stationsstraat 102
Mechelen
2800
Belgium

Nobel Biocare AB, Produktion
Verkstadsgatan 1-5
Karlskoga
691 50
Sweden

Registered Activities

The design, manufacture and distribution of software applications for oral, extra oral and cranio-maxillofacial surgical solutions.

The manufacture of oral and extra oral prosthetic reconstruction solutions, endosseous implants, abutments and other associated dental instruments and accessories.



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