

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, marketing, warehousing, sales, order processing, assembly, kitting, packaging, 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 provision of training programs. The marketing, sales and distribution of porcine dental membranes, bovine bone graft and bovine bone graft with porcine collagen.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2004-03-03

Latest Revision Date: 2020-10-02

Effective Date: 2020-10-06

Expiry Date: 2021-04-05

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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 design, marketing and 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 provision of training programs. The marketing, sales and distribution of porcine dental membranes, bovine bone graft and bovine bone graft with porcine collagen.
Nobel Biocare AB, Produktion Dimbovägen 2 Karlskoga 691 51 Sweden	The manufacture, assembly, packaging and distribution 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, assembly, packaging, marketing, sales, order processing, warehousing and distribution of endosseous implants, abutments, dental kits and other associated dental instruments and accessories. The marketing, sales and distribution of oral and extra oral prosthetic reconstruction solutions, abutments, porcine dental membranes, bovine bone graft and bovine bone graft with porcine collagen. The provision of training programs.
Nobel Biocare Procera, LLC 800 Corporate Drive Mahwah New Jersey 07430 USA	The manufacture, packaging, order processing, and distribution of oral prosthetic reconstruction solutions, software applications for oral, extra oral and cranio-maxillofacial surgical solutions, abutments, crowns and bridges. The provision of training programs.
Nobel Biocare Japan K.K. 13F Gotenyama Trust Tower 4-7-35 Kitashinagawa Shinagawa-ku 140-0001 Japan	The marketing, sales, warehousing and distribution of oral and extra oral prosthetic reconstruction solutions, abutments, dental kits, crowns and bridges, software applications for oral, extra oral and cranio-maxillofacial surgical solutions, endosseous implants, and other associated dental instruments and accessories. The provision of training programs.
Nobel Biocare Distribution Center B.V. Kozakkenberg 4 Belfeld 5951 DL The Netherlands	The warehousing, assembly, kitting and distribution of oral and extra oral prosthetic reconstruction solution, dental kits, planning software, endosseous implants, abutments, other associated dental instruments and accessories. The distribution of porcine dental membranes, bovine bone graft and bovine bone graft with porcine collagen.

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Location	Registered Activities
Nobel Biocare Procera K.K. 3-6-2 Akanehama Narashino-shi Chiba 275-0024 Japan	The manufacture, packaging, order processing, and distribution of oral prosthetic reconstruction solutions, software applications for oral, extra oral and cranio-maxillofacial surgical solutions, abutments, dental kits, crowns and bridges. The provision of training programs.
Nobel Biocare Services AG Balz-Zimmermann-Strasse 7 Kloten 8302 Switzerland	The design, marketing, sales, control of manufacture and supply 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 marketing, sales and distribution of porcine dental membranes, bovine bone graft and bovine bone graft with porcine collagen. The provision of training programs.
Nobel Biocare c/o Medicim NV Stationsstraat 102 Mechelen 2800 Belgium	The design and manufacture of software applications for oral, extra oral and cranio-maxillofacial surgical solutions.
Nobel Biocare AB, Produktion Verkstadsgatan 1-5 Karlskoga 691 50 Sweden	The manufacture, assembly, packaging and distribution of oral and extra oral prosthetic reconstruction solutions, endosseous implants, abutments and other associated dental instruments and accessories.

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