

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nobel Biocare AB
PO Box 5190, SE-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 for the following scope:

The design, manufacture, warehousing, marketing, sales, order processing and distribution of oral and extra oral prosthetic reconstruction solutions, dental kits, endosseous implants, abutments, crowns, bridges and other associated dental instruments 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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-03-03

Latest Revision Date: 2017-10-05

Effective Date: 2017-10-06

Expiry Date: 2020-10-05



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Certificate No: MD 81731

Location	Registered Activities
Nobel Biocare AB PO Box 5190, SE-402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden	The design, marketing and sales of oral and extra oral titanium and ceramic prosthetic reconstruction solutions, planning software, endosseous implants, abutments, crowns, bridges and other associated dental instruments. 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 2 691 51 Karlskoga Sweden	The manufacture and distribution of oral and extra oral prosthetic reconstruction solutions, endosseous implants, abutments and other associated dental instruments.
Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda California 92887 USA	The manufacture, packaging, marketing, sales, warehousing and distribution of implants, abutments, dental kits and other associated dental instruments. The marketing, sales and distribution of oral and extra oral prosthetic reconstruction solutions, abutments, crowns and bridges, planning software and 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 design, manufacture and distribution of oral prosthetic reconstruction 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 Tokyo 140-0001 Japan	The marketing, sales, warehousing and distribution of oral and extra oral prosthetic reconstruction solutions, abutments, crowns and bridges, planning software, endosseous implants, and other associated dental instruments. The provision of training programs.
Nobel Biocare Distribution Center B.V. Kozakkenberg 4 Belfeld 5951 DL The Netherlands	The warehousing, assembly and distribution of oral and extra oral prosthetic reconstruction solution, dental kits, planning software, endosseous implants, abutments and other associated dental instruments. 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 and distribution of oral prosthetic reconstruction solutions, abutments, crowns and bridges.
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, planning software, 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.
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.



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