

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

DUNS Number: 35-393-9929

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, marketing and sales, and warehousing 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.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-02-12

Effective Date: 2020-02-05

Expiry Date: 2021-10-05



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 DUNS Number: 35-393-9929	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 DUNS Number: 35-332-3278	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 DUNS Number: 60-945-7494	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, crowns and bridges, 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 DUNS Number: 82-501-9123	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 Distribution Center B.V. Kozakkenberg 4 Belfeld 5951 DL The Netherlands DUNS Number: 40-952-4472	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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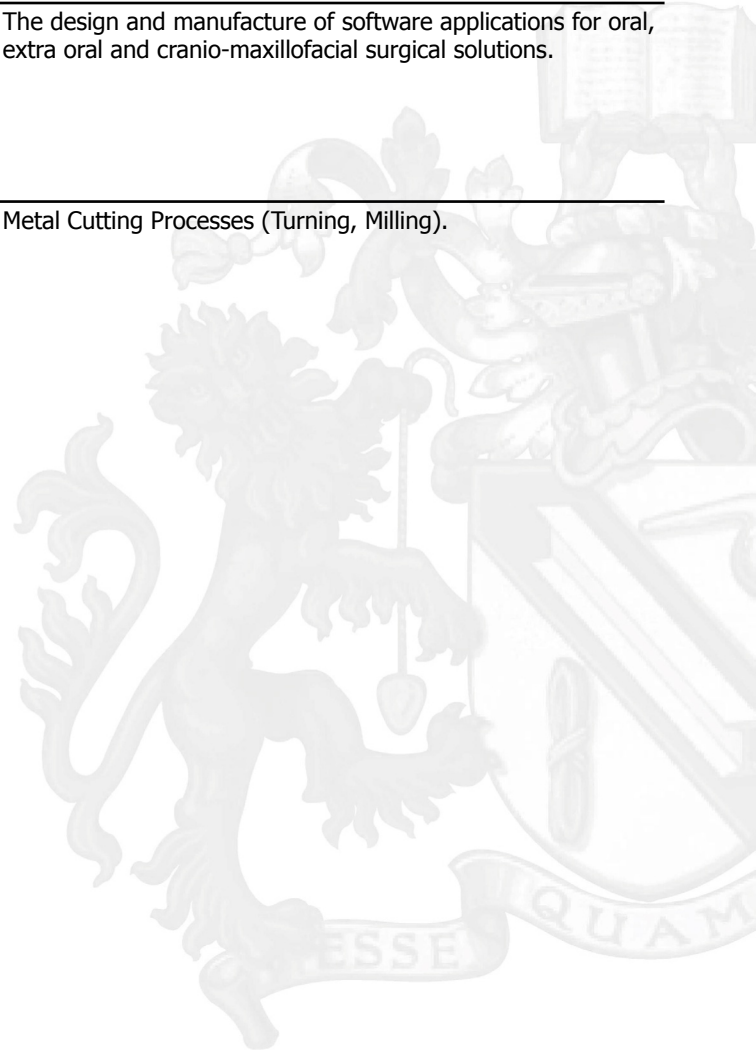
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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

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Location	Registered Activities
Nobel Biocare Services AG Balz-Zimmermann-Strasse 7 Kloten 8302 Switzerland DUNS Number: 48-221-7069	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 DUNS Number: 37-281-6343	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 DUNS Number: 35-393-9929	Metal Cutting Processes (Turning, Milling).



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