EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 717177 R000

Manufacturer: Nobel Biocare AB

Address:
PO Box 5190, 402 26
Västra Hamngatan 1
Göteborg
411 17
Sweden

Single Registration Number: SE-MF-000000009

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2020-04-09** Date: **2022-06-28** Expiry Date: **2025-04-08**

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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable, Well-established technologies	Intended purpose
Dental Implants	Intended for use as an endosseous dental implant in the maxilla or mandible for anchoring or supporting dental prostheses to restore chewing function. Intended for use as a dental implant in the zygomatic bone for anchoring or supporting dental prostheses to restore chewing function.
Abutments	Intended to be finalized into a single-unit dental prosthesis, which is connected to an endosseous dental implant to restore chewing function. Intended to be temporarily connected to an endosseous dental implant or implant abutment to support healing of the surrounding soft tissue.
Dental Screws	Intended for use to fasten dental implant system components to a dental implant or to another component.
Oral and extra-oral prosthetic reconstruction solutions	Intended to be finalized into a multi-unit dental prosthesis, which is connected to endosseous dental implants to restore chewing function.

Class IIb	Intended purpose
Odontostomatology software	Intended purpose of the software is to support the diagnostic process and treatment planning for dental and cranio-maxillofacial procedures.

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Odontostomatology Instruments	Class IIa
Reusable instruments 'Odontostomatology Instruments'	Class Ir
Reusable instruments 'Odontostomatology Instruments'	Class Ir & m
Dental planning software	Class Im
For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements. For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2020-04-09	3070186	Issued.
2021-03-02	3371044	Supplemented – Addition of the following device groups - Dental Implants, Abutments, Dental Screws, Oral and extra-oral prosthetic reconstruction solutions, Odontostomatology Instruments. Amended – Addition of BBF Sterilisationsservice GmbH, BGS Beta-Gamma-Service GmbH & Co. KG, Gebr. Brasseler GmbH & Co. KG , Isomedix Operations, Inc, Nobel Biocare Procera, LLC, Nobel Biocare Procera K.K. to the list of significant subcontractors. Removal of subcontractor 'Nobel Biocare Distribution Centre B.V.'. Activity for subcontractor 'Nobel Biocare USA, LLC' updated to 'manufacture' (removal of 'assembly').
Current	3698276	Supplemented – Addition of device group 'Odontostomatology software' Amended – Change of subcontractor name from 'La Precision' to 'La Precision Industry'. Administrative updates to history page.

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 717177 R000

Date: **2022-06-28**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	**Radiation (Gamma Sterilization)**
BGS Beta-Gamma-Service GmbH & Co. KG John-Deere-Straße 1 + 3 76646 Bruchsal Germany	**Radiation (Gamma Sterilization)**
Elos Medtech Pinol A/S Engvej 33 Gørløse 3330 Denmark	**Manufacture**
Gebr. Brasseler GmbH & Co. KG Trophagener Weg 25 32657 Lemgo Germany	**Manufacture**
HIPP Medical AG Wilhelmstraße 19 78600 Kolbingen Germany	**Manufacture**
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	**Radiation (Gamma Sterilization)**

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Critical Subcontractor/Crucial Supplier	Service(s) supplied
La Precision Industry 16 rue des horlogers 74950 SCIONZIER France	**Manufacture**
Nobel Biocare AB, Produktion Dimbovägen 2 691 51 Karlskoga Sweden	**Manufacture**
Nobel Biocare AB, Produktion Verkstadsgatan 1-5 691 50 Karlskoga Sweden	**Manufacture**
Nobel Biocare c/o Medicim NV Stationsstraat 102 2800 Mechelen Belgium	**Design** **Manufacture**
Nobel Biocare Procera K.K 3-6-2 Akanehama Narashino-shi Chiba 275-0024 Japan	**Manufacture**
Nobel Biocare Procera, LLC 800 Corporate Drive Mahwah New Jersey 07430 USA	**Manufacture**

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Date: **2022-06-28**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Nobel Biocare Services AG Balz Zimmermann-Strasse 7 8302 Kloten Switzerland	**Design** **Regulatory Compliance**
Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda California 92887 USA	**Manufacture**
Synergy Health AST, Ede a Steris Company Morsestraat 3 Ede 6716 AH The Netherlands	**Radiation (Gamma Sterilization)**

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