By Royal Charter

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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