

EU Quality Management System Certificate

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

MDR 717177 R001

Manufacturer: Nobel Biocare AB

Address:

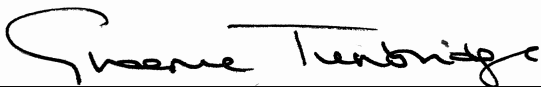
PO Box 5190, 402 26
Västra Hamngatan 1
Göteborg
411 17
Sweden

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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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 Global Regulatory & Quality

First Issue Date: **2020-04-09**

Current Issue Date: **2025-10-08**

Starting Validity Date: **2025-10-08**

Expiry Date: **2030-04-08**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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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 a dental implant to restore chewing function.
Dental Abutments	Intended to be connected to a dental implant or implant abutment to support healing of the surrounding soft tissue or to support the placement of a dental prosthesis.
Dental Screws	Intended for use to fasten dental implant system components to a dental implant or to protect the implant connection during healing.
Oral and Extra-Oral Prosthetic Reconstruction Solutions	Intended to be finalised into a multi-unit dental prosthesis or bar overdenture, which is connected to dental implants.
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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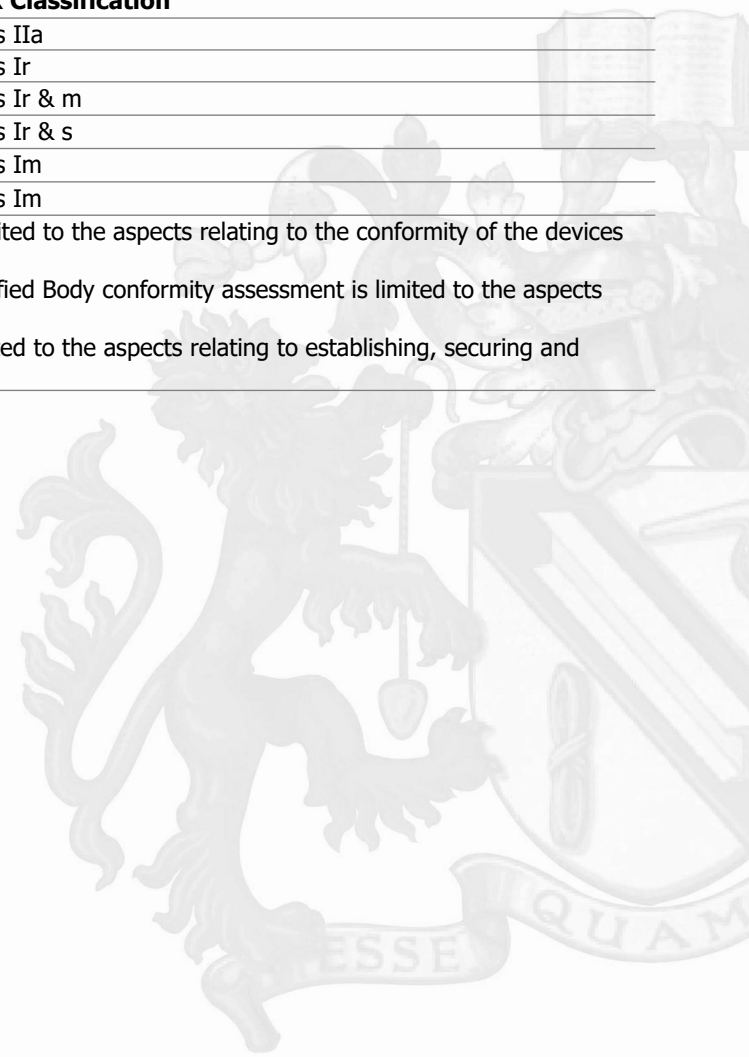
Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Odontostomatology Instruments	Class IIa
Reusable instruments 'Odontostomatology Instruments'	Class Ir
Reusable instruments 'Odontostomatology Instruments'	Class Ir & m
Reusable instruments 'Odontostomatology Instruments'	Class Ir & s
Odontostomatology Instruments	Class Im
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.

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.



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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.

A Member of the BSI Group of Companies.

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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 following device groups – Dental Implants, Abutments, Dental Screws, Oral and Extra-oral Prosthetic Reconstruction Solutions, Odontostomatology Instruments Amended – Addition and removal of subcontractors for manufacturing and sterilisation.
2022-06-28	3698276	Supplemented – Addition of device group 'Odontotomatology Software' Amended – Change of subcontractor name. Administrative updates to history page.
2025-03-18	30223465	Re-Issued – Certificate Renewal Amended – Administrative update to previous entries Reference Number 3371044 and 3698276. Change of intended purpose of "Dental Implants", "Abutments", "Dental Screws" and "Oral and Extra-Oral Prosthetic Reconstruction Solutions". Change of "Abutments" to "Dental Abutments". Addition of subcontractor for Sterilisation.
Current	30541996	Amended – Addition of subcontractor Supplemented – Addition of device category Reusable instruments 'Odontostomatology Instruments' (Class Ir & s). Supplemented – Addition of device category Odontostomatology Instruments Class Im.

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