

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

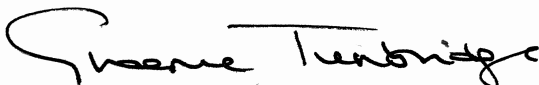
No. UKCA 773670
Issued To: Nobel Biocare AB
PO BOX 5190, 402 26
Västra Hamngatan 1
Göteborg
411 17
Sweden

In respect of:

See certificate scope page.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-11-08**

Date: **2022-11-08**

Expiry Date: **2025-04-08**

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Certificate No: UKCA 773670

Certificate Scope:

The design, manufacture and final inspection of:

- **Sterile Dental Implants**
- **Sterile and Non-sterile Dental Abutments**
- **Non-sterile Prosthetic Reconstruction Solutions**
- **Sterile and Non-sterile Dental Screws**
- **Sterile and Non-sterile Dental Instruments**

Those aspects of Annex II relating to metrology of software applications supporting oral, extra-oral and cranio-maxillofacial treatments.

Those aspects of Annex II relating to metrology of instruments and accessories for dental surgery.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Supplementary Information to UKCA 773670

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Device code	Device name	Intended purpose per IFU
Class IIb		
55849	Dental Implants	Intended for use as a dental implant in the zygomatic bone for anchoring or supporting dental prostheses to restore chewing function. 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 an endosseous dental implant in the mandible for anchoring or supporting dental prostheses to restore chewing function.
44879	Dental Abutments	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis. Intended to be finalized into a single-unit dental prosthesis, which is connected to an endosseous dental implant to restore chewing function. Intended for use as part of a pre-manufactured definitive bar used for the fabrication of a final dental prosthesis. Intended for use as a component of a dental implant-supported bar overdenture system for the fabrication and/or placement of a final dental prosthesis.
44880		Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis. Intended to be temporarily connected to an endosseous dental implant or implant abutment to support healing of the surrounding soft tissue.

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Device code	Device name	Intended purpose per IFU
44879	Prosthetic Reconstruction Solution	Intended to be finalized into a multi-unit dental prosthesis, which is connected to endosseous dental implants to restore chewing function.
61647	Dental Screws	Intended for use to fasten dental implant system components to a dental implant or to another component.
44880		Intended to be temporarily connected to an endosseous dental implant or implant abutment to support healing of the surrounding soft tissue. Intended to be temporarily connected to an endosseous dental implant to protect the implant connection interface during bone healing.
Class IIa		
MD 0401	Odontostomatology Instruments	---
Class Im		
MD 0401	Odontostomatology Instruments	---
MD 1111	Odontostomatology Software	---

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Certificate History

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Date	Reference Number	Action
Current	3703893	First Issue, Traceable to MDR 717177

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