

# 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]

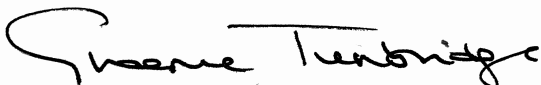
**No.** **UKCA 773670**  
Issued To: **Nobel Biocare AB**  
**PO BOX 5190, 402 26**  
**Västra Hamngatan 1**  
**Göteborg**  
**411 17**  
**Sweden**

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 Global Regulatory & Quality

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

Date: **2025-10-08**

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

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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.

Certificate No: UKCA 773670

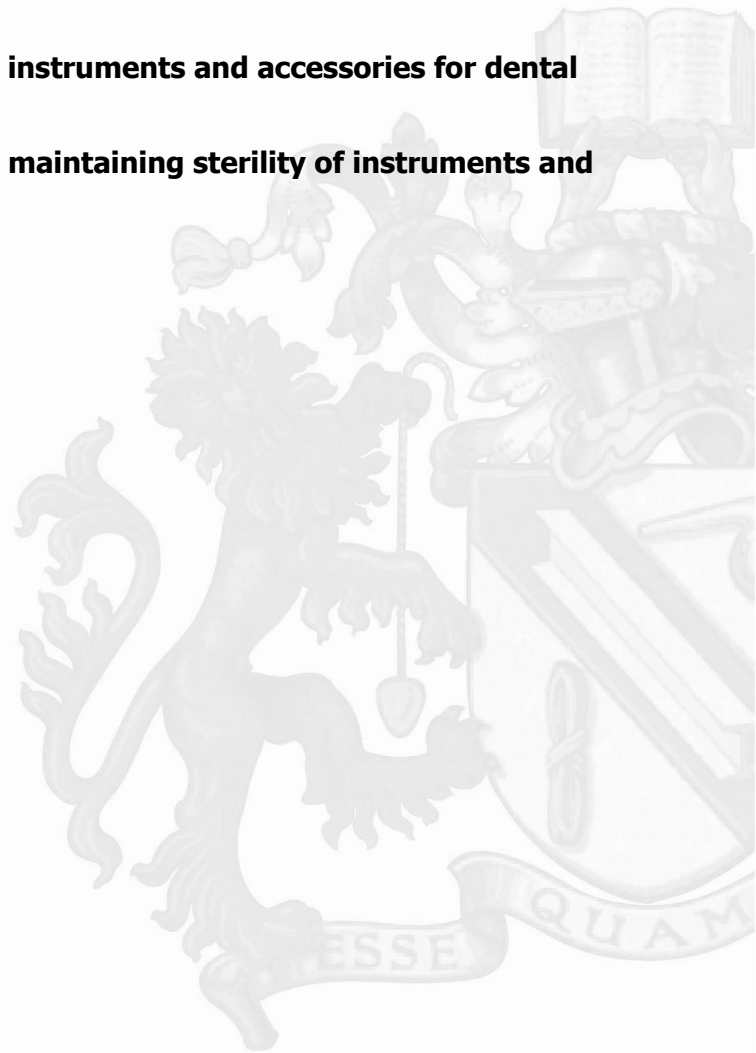
## Certificate Scope:

**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 and 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.**

**Those aspects of Annex II relating to securing and maintaining sterility of instruments and accessories for dental surgery.**

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## Supplementary Information to UKCA 773670

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Device code	Device name	Intended purpose per IFU
<b>Class IIb</b>		
55849	Dental Implants	Intended for use as a dental implant to restore chewing function.
44879	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.
44880		
44879	Prosthetic Reconstruction Solution	Intended to be finalised into a multi-unit dental prosthesis or bar overdenture, which is connected to dental implants.
61647	Dental Screws	Intended for use to fasten dental implant system components to a dental implant or to protect the implant connection during healing.
44880		
<b>Class IIa</b>		
MD 0401	Odontostomatology Instruments	---
<b>Class Im</b>		
MD 0401	Odontostomatology Instruments	---
MD 1111	Odontostomatology Software	---
<b>Class Is</b>		
MD 0401	Odontostomatology Instruments	---

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## Certificate History

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Date	Reference Number	Action
2022-11-08	3703893	First Issue; Traceable to MDR 717177
2025-03-18	30362423	Renewal Change of intended purpose for "Dental Implants", "Dental Abutments", "Prosthetic Reconstruction Solutions", "Dental Screws".
Current	30541998	Addition of subcontractor Addition of new device category Odontostomatology Instruments, Class Is.

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