

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 00353  
**Issued To:** Nobel Biocare AB  
PO Box 5190, 402 26  
Västra Hamngatan 1  
Göteborg  
411 17  
Sweden

In respect of:

**The design and manufacture of oral and extra-oral prosthetic reconstruction solutions, endosseous implants, abutments, other associated dental instruments and Surgical Kits.**

**Those aspects of Annex II related to metrology in the design and manufacture of software applications supporting oral, extra-oral and cranio-maxillofacial treatments.**

**Those aspects of Annex II concerned with metrological requirements of instruments and accessories for dental surgery**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1994-12-05**

Date: **2019-10-31**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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