

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
411 17 Göteborg
Sweden

In respect of:

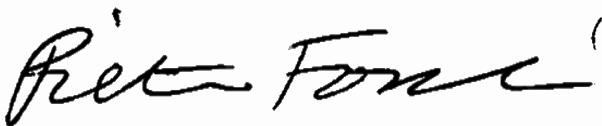
The design and manufacture of oral and extra-oral prosthetic reconstruction solutions, endosseous implants, abutments, crowns, bridges, other associated dental instruments and Surgical Kits.

Those aspects of Annex II related to metrology in the design and manufacture of software applications for oral reconstruction solutions.

Those aspects of Annex II related to the conformity of Class I Measuring devices with the metrological requirements.

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 0086):



Pietro Foschi - Strategic Delivery Director

First Issued: **05 December 1994**

Date: **03 December 2014**

Expiry Date: **04 December 2019**

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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.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Date: **03 December 2014**
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Subcontractor:	Service(s) supplied
Cendres + Métaux SA Rue de Boujeau 122 Biel / Bienne CH-2501 Switzerland	Design Manufacture
Elos AB Nya Stadens Torg 10 Lidköping SE-531 31 Sweden	Manufacture
Elos Medtech Pinol A/S Engvej 33 Görlöse 3330 Denmark	Manufacture
Gebr. Brasseler GmbH & Co. KG Trophagener Weg 25 32657 Lemgo Germany	Design Manufacture

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Subcontractor:	Service(s) supplied
La Precision 16 rue des Horlogers Boîte Postale 2 SCIONZIER Cedex 74950 France	Manufacture
Nobel Biocare AB, Procera Västbergavägen 26 SE-126 30 Hägersten Sweden	Design Manufacture
Nobel Biocare AB, Produktion Dimbovägen 2 SE-691 51 Karlskoga Sweden	Manufacture
Nobel Biocare Distribution Centre BV Industrial Zone No 7708 5951 DL Belfeld Netherlands	Assembly Warehousing

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Subcontractor:	Service(s) supplied
Nobel Biocare Management AG & Nobel Biocare Services AG Balz Zimmermann-Strasse 7 CH-8302 Kloten Switzerland	Design Regulatory Compliance
Nobel Biocare Procera K.K. 3-6-2 Akanehama Narashino-shi Chiba 275-0024 Japan	Manufacture
Nobel Biocare Procera Services Inc. 750 Blvd du parc technologique Québec Québec G1P 4S3 Canada	Manufacture

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Nobel Biocare Procera, LLC 800 Corporate Drive Mahwah New Jersey 07430 USA	Design Manufacture
Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda California 92887 USA	Assembly Manufacture Warehousing
Nobel Biocare Stationsstraat 102 Mechelen B-2800 Belgium	Design Manufacture

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Subcontractor:	Service(s) supplied
Orchid MPS 3233 W. Harvard Street Santa Ana California 92704 USA	Manufacture
Sterigenics International, Inc. 2015 Spring Road Suite 650 Oak Brook Illinois 60523 USA	Sterilization
STERIS Isomedix Services 1880 Industrial Drive Libertyville Illinois 60048 USA	Sterilization

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Subcontractor:

Service(s) supplied

Synergy Health AST, Ede
Morsestraat 3
6716 AH Ede
Netherlands

Gamma Sterilization

Synergy Health AST, Etten-Leur
Soeverinstraat 2
4879 NN Etten-Leur
Netherlands

Gamma Sterilization

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