

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**

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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: **2019-10-31**
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Göteborg
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Subcontractor:	Service(s) supplied
Cendres + Métaux SA Rue de Boujean 122 Biel / Bienne CH-2501 Switzerland	Design Manufacture
Doceram Medical Ceramics GmbH 65-67 Hesslingsweg Dortmund 44309 Germany	Crucial Supplier
Elos Medtech Pinol A/S Engvej 33 Gørløse 3330 Denmark	Manufacture

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Subcontractor:	Service(s) supplied
Gebr. Brasseler GmbH & Co. KG Trophagener Weg 25 Lemgo 32657 Germany	Design Manufacture
HIPP Medical AG Wilhelmstraße 19 Kolbingen 78600 Germany	Manufacture
KSP GmbH CNC- Technik Josef-Beyerle-Strasse 14 Weil der Stadt 71263 Germany	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, Produktion Dimbovägen 2 691 51 Karlskoga Sweden	Manufacture
Nobel Biocare c/o Medicim NV Stationsstraat 102 Mechelen B-2800 Belgium	Design Manufacture
Nobel Biocare Distribution Centre BV Kozakkenberg 4 5951 DL Belfeld The Netherlands	Assembly

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Subcontractor:	Service(s) supplied
Nobel Biocare Procera K.K 3-6-2 Akanehama Narashino-shi Chiba 275-0024 Japan	Manufacture
Nobel Biocare Procera, LLC 800 Corporate Drive Mahwah New Jersey 07430 USA	Manufacture
Nobel Biocare Services AG Balz Zimmermann-Strasse 7 CH-8302 Kloten Switzerland	Design Regulatory Compliance

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Subcontractor:	Service(s) supplied
Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda California 92887 USA	Assembly Manufacture
Orchid MPS A division of Orchid Orthopedic Solutions, LLC 3233 W. Harvard Street Santa Ana California 92704 USA	Manufacture
Perryman Company 213 Vandale Drive Houston Pennsylvania 15342 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
STERIS Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	Gamma Sterilization
Synergy Health AST, Ede Morsestraat 3 Ede 6716 AH The Netherlands	Gamma Sterilization
Titanium Industries, Inc. 18 Green Pond Road Rockaway New Jersey 07866 USA	Crucial Supplier

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Subcontractor:

Service(s) supplied

Tosoh Corporation Nanyo Complex
4560, Kaisei-cho
Shunan-shi
Yamaguchi
746-8501
Japan

Crucial Supplier

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Date	Reference Number	Action
05 December 1994	-	First Issue.
19 May 1995	-	Change of address details.
11 June 1996	-	Company name change to Nobel Biocare AB.
24 November 1997	-	Karlskoga site converted to a sub-contractor and Nobel Biocare Manufacturing Inc added to list of sub-contractors.
14 September 1998	-	"Prosthetic components" added to the scope. Flexible Medical Packaging LTD and Caterpillar Logistics Services added to list of sub-contractors, Nobel Biocare Manufacturing Inc deleted from list of sub-contractors.
09 February 1998	-	"Bone Anchored Hearing Aids" deleted from the scope. LR Plast A/S, Tremedic Industries AB and Medical Rubber AB added to list of sub-contractors.
02 December 2002	-	5-year Renewal. Nobel Biocare USA INC, Nobel Biocare Procera AB (Stockholm), Gammaster BV (EDE), Gammaster BV (ETTEN LEUR) and Maillefer Instruments SA added to the list of sub-contractors.
07 July 2003	-	Change of name of Gammaster B.V. to Isotron Nederland B.V. and the addition of Nobel Biocare Procera Inc (Fair Lawn) to the list of sub-contractors.

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02 January 2004	-	Change to address details. LR Plast A/S deleted from a list of sub-contractors. Activity of Maillefer Instruments S/A changed to read "Design and manufacture of instruments for dentistry, surgery and jewellery".
25 February 2004	-	Scope adjusted to define some of the products more specifically.
10 January 2005	-	Change of name and address of Nobel Biocare sites and 5-year renewal.
31 January 2005	-	Reformat of Subcontractor address.
04 October 2005	-	Change of scope to remove "and extraoral".
01 October 2007	-	Extension to scope to include "development, extra-oral titanium and ceramic, reconstruction solutions, abutments, crowns, and bridges". Addition of 2 new subcontractors, "Nobel Biocare Procera K.K., Japan as manufacturing subcontractor activity and Nobel Biocare Distribution Centre BV, Netherlands as assembly and warehousing subcontractor activities".
20 October 2008	7281347	Addition of Brasseler GmbH, Germany, to the list of significant subcontractors for design and manufacture.

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24 November 2009	7296965	Addition of Nobel Biocare Procera Services Inc. Canada, to the list of significant subcontractors for manufacture. Remove moist heat sterilization from the activities of the Isotron locations. Certificate Renewal.
14 April 2010	7491048	Replacement of "titanium" in certificate scope with "metal".
10 June 2010	7482569	Deletion of "metal and ceramic" from scope.
23 February 2011	7632455	Addition of subcontractor, 'Nobel Biocare Management AG Nobel Biocare Services AG, Kloten, Switzerland' for Design and Regulatory Compliance activities.
22 February 2012	7795422	Change of address for Nobel Biocare AB from Bohusgatan, Göteborg, Sweden, to Västra Hamngatan, Göteborg, Sweden. Name change of significant subcontractor Isotron Nederland B.V., Ede to Synergy Health AST, Ede and name change of significant subcontractor Isotron Nederland BV, Etnen-Leur to Synergy Health AST, Etnen-Leur Bohusgatan added as a significant subcontractor.

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Date	Reference Number	Action
21 August 2014	8179086	Addition of "Nobel Biocare, Stationsstraat 102, Mechelen, B-2800 Belgium" to the list of significant subcontractors for design and manufacturer of software applications. Extension to scope to include those aspects of Annex II related to metrology aspects in the design and manufacture of software applications. Remove word "development" from the scope.
03 December 2014	8251808	Certificate Renewal. Extension to scope to include "Surgical Kits" and "aspects of Annex II related to the conformity of Class I Measuring devices with the metrological requirements". Removal of Significant subcontractor "Maillefer Instruments SA" for Design and Manufacture activities and "Nobel Biocare AB" for manufacture activity. Addition of significant subcontractors "La Precision", "Elos AB", "Elos Medtech Pinol A/S", "Cendres + Métaux SA" and "Orchid MPS" for Manufacture activities, and "Sterigenics International, Inc." and "Steris Isomedix Services" for Sterilization activities. Change to the activities performed by the subcontractors: Nobel Biocare USA, LLC and Nobel Biocare Procera, LLC to ensure the service supplied at those locations.

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Date	Reference Number	Action
14 September 2015	8315386	<p>Removal of location; Nobel Biocare Procera Services Inc, 750 Blvd du parc technologique, Québec, G1P 4S3.</p> <p>Addition of crucial suppliers; Biesterfeld spezialchemie (41 Ferdinandstr, Hamburg 20095, Germany), Dentaforum GmbH & Co. KG (Turnstraße 31, 75228 Ispringen, Germany), Doceram Medical Ceramics GmbH (65-67 Hesslingsweg, Dortmund 44309, Germany), Dynamet Incorporated (Suite 221, 16052 Beach Blvd, Huntington Beach, USA), Perryman Company (213 Vandale Drive, Houston 15342, USA), Sumitono Shoji Chemicals KK (Harumi Island Triton Square Office Tower Z, 8-12, Harumi 1-chome, Chuo-ku, Tokyo 104-6224) and Titanium Industries Inc (18 Green Pond Road Rockaway, NJ USA 07866).</p> <p>Ivoclar Vivadent AG (Bendererstrasses 2, FL-9494 Schaan, Liechtenstein), Ivoclar Vivadent Inc (175 Pineview Dr, Amherst, NY 14228, USA), Ivoclar Vivadent KK (1-28-24-4F Hongo, Bunkyo-ku, Tokyo 113-0033, Japan), Titanium Industries Inc (127, Montée-de-Liesse, St. Laurent, Québec, H4T 1T9, Canada), Tosoh K.K. (3-8-2, Shiba, Minato-ku, Tokyo, 105-8623, Japan) and Tosoh Europe B.V. (Crown Building South, Hullenbergweg 359, 1101 CP Amsterdam Z.O., Netherlands) .</p> <p>Change of name from Nobel Biocare (Stationsstraat 102, Mechelen, B-2800, Belgium) to Nobel Biocare c/o Medicim NV.</p>

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30 March 2016	8466568	Addition of manufacturing subcontractors; HIPP Medical AG (Wilhelmstraße 19, 78600 Kolbingen, Germany) and KLINGEL medical metal GmbH (Hanauer Straße 5-7, 75181 Pforzheim, Germany) Removal of Crowns and Bridges from the scope Extension to scope to 'Those aspects of Annex II related to metrology in the design and manufacture of software applications for oral and cranio-maxillofacial reconstruction solutions'.
08 December 2016	8632595	Addition of extra-oral software to scope Removal of subcontractors/suppliers: Biesterfeld Spezialchemie GmbH, Dynamet Incorporated, Elos AB, Nobel Biocare AB (Hägersten), Sterigenics International, Inc, Sumitono Shoji Chemicals KK, Synergy Health AST, Etten-Leur. Addition of KSP GmbH CNC-Technik, Josef-Beyerle-Strasse 14, Weil der Stadt 71263, Germany as manufacturing subcontractor. Replacement of 'for' with 'supporting' Replacement of 'reconstruction solutions' with 'treatments'. Scope clarification to 'Those aspects of Annex II concerned with metrological requirements of instruments and accessories for dental surgery'.
15 May 2017	8728441	Clarification of address to: PO Box 5190, SE-402 26, Västra Hamngatan 1, Göteborg, 411 17, Sweden.

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Date	Reference Number	Action
13 August 2018	8957282	Removal of crucial suppliers Ivoclar Vivadent Inc and Ivoclar Vivadent KK. Removal of manufacturer KLINGEL medical metal GmbH. Update to subcontractor name and correction of subcontractor address.
09 January 2019	7779005	Traceable to NB 0086.
Current	9689451	Certificate Renewal. Removal of Crucial Suppliers: Dentaurum GmbH & Co. KG, IVOCLAR VIVADENT AG, TITANIUM Industries Inc., TOSOH Europe B.V. Minor correction to subcontractor address: Cendres + Métaux SA. Change of subcontractor name and address: STERIS Isomedix Operations Inc. and Tosoh Corporation Nanyo Complex. Removal of Design activity for: Nobel Biocare Procera, LLC.