

Certificate

Full Quality Assurance

No. CE 00353



Issued to:

Nobel Biocare AB
PO Box 5190, SE-402 26
Bohusgatan 15
411 39
Göteborg
Sweden

In respect of:

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

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'D. W. Ford', with a horizontal line underneath.

David W. Ford, Executive Director, Healthcare and Testing Services

First Issued: 5 Dec 1994

Date: 23 Feb 2011

Expiration Date: 4 Dec 2014

Page: 1 of 1

Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

raising standards worldwide™



List of Significant Subcontractors

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

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Subcontractor	Service(s) supplied
Brasseler GmbH & Co. KG Trophagener Weg 25 32657 Lemgo Germany	Design Manufacture
Nobel Biocare Management AG & Nobel Biocare Services AG Balz Zimmermann-Strasse 7 CH-8302 Kloten Switzerland	Design Regulatory Compliance
Nobel Biocare AB, Produktion Dimbovägen 2 SE-691 51 Karlskoga Sweden	Manufacture
Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda CA 92887 USA	Design Manufacture
Nobel Biocare AB, Procera Västbergavägen 26 SE-126 30 Hägersten Sweden	Design Manufacture

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Subcontractor	Service(s) supplied
Nobel Biocare Procera, LLC 800 Corporate Drive Mahwah NJ 07430 USA	Manufacture
Isotron Nederland B.V. P.O. Box 600 67 10 BP EDE Netherlands	Gamma Sterilization
Isotron Nederland BV PO Box 357-4870 AJ Etten-Leur Soevereinstraat 2 4879-NN Etten-Leur Netherlands	Gamma Sterilization
Maillefer Instruments SA CH-1338 Baillaigues Switzerland	Design Manufacture
Nobel Biocare Procera K.K. 3-6-2 Akanehama Narashino-shi Chiba 275-0024 Japan	Manufacture

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Subcontractor	Service(s) supplied
Nobel Biocare Procera Services Inc. 750 Blvd du parc technologique Québec Québec G1P 4S3 Canada	Manufacture
Nobel Biocare Distribution Centre B Industrial Zone No 7708 5951 DL Belfeld Netherlands	Assembly Warehousing

History of Quality Assurance Certificate

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Date	BSI Reference	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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Date	BSI Reference	Action
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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Date	BSI Reference	Action
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