By Royal Charter

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, SE-402 26
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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):

Albert Roossien, Regulatory Lead

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