

EC Certificate - Full Quality Assurance System

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

No. CE 99641
Issued To: **DEXCOWIN Co., Ltd.**
#606, 2, Gasan digital 1-ro
Geumcheon-gu
Seoul
153-776
Republic of Korea

In respect of:

The design and manufacture of portable dental X-ray systems and digital radiography systems.

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **23 September 2005**

Date: **30 April 2015**

Expiry Date: **22 September 2015**

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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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Subcontractor:

Service(s) supplied

Boston Dental Scientific
c/o Isabel Colbrand 10
Local 68
28050 Madrid
Spain

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
23 September 2005	4739767	First Issue
15 April 2008	7187136	Certificate re-issue to reflect change in company address
28 September 2010	7475418	Certificate renewal, also addition of Boston Dental Scientific as the EU representative
30 April 2015	8285949	Certificate re-issue due to scope extension to include digital radiography systems and change of address.

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