

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 588583**

Issued To:

**Wellspect HealthCare
(a division of Dentsply IH AB)
Aminogatan 1
PO Box 14
SE-431 21 Mölndal
Sweden**

In respect of:

Those aspects of Annex V concerned with securing and maintaining sterility of urology and urotherapy devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2012-08-20**Date: **2020-10-22**Expiry Date: **2024-03-31****...making excellence a habit.™**

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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.