

EC Certificate - Production Quality Assurance

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

No.**CE 607665**

Issued To:

**Medeco BV
Alexander Flemingstraat 2
3261 MA Oud-Beijerland
Netherlands**

In respect of:

Those aspects of Annex V concerned with securing and maintaining the sterility of urinary catheters and accessories, medical devices for wound care and intraoperative use, examination products for General Practitioners and surgical suite products.

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **24 June 2016**Date: **24 June 2016**Expiry Date: **01 February 2021**

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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.