By Royal Charter

# EC Certificate - Production Quality Assurance

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

**No.** **CE 567925**

Issued To: **Medica Europe B.V.**
**Galliersweg 20**
**Oss**
**5349 AT**
**Netherlands**

In respect of:

**See certificate scope page.**

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: **01 December 2010** Date: **14 January 2016** Expiry Date: **30 November 2020**

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Certificate No: CE 567925

# Certificate Scope:

**Manufacture of devices (see supplementary page) to administer, withdraw or/and store body fluids, tissues, liquids and / or gasses for therapeutic and/or diagnostic purposes, and devices for prevention of contamination of the surgical theatre.**
**Manufacture of surgical procedure products and body organ/tissue transporting/storage products.**
**Manufacture of custom procedure trays intended to be used for cardiovascular, orthopaedic, EENT, general surgery, gynaecology and obstetrics, urology, neurosurgery, anaesthesia, ICU, angiography and biopsy applications and custom replacement sets.**
**Manufacture of cryogenic spray for skin cooling.**
**Those aspects of Annex V related to securing and maintaining sterility of medical scrub brushes for mechanical cleaning.**
**Those aspects of Annex V related to the securing and maintaining of sterility in the assembly of procedure packs in accordance with Article 12**

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**Supplementary Information to CE 567925**

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Drawn off systems
Administration products
Nutrition probes
Accessories for administration systems
Accessory systems for pressure monitoring devices
Drains/suction systems
Curette systems
Storage and transport systems of body organs/tissues
Systems for administration of contrast fluids
Ureter catheters
Non surgical rinsing systems
Artificial respiration systems
Medicinal administration products
Administration accessory products
Rectal canula
Extension and interconnecting tubes
Withdrawal products (draw off systems)
Preventive microbial accessory products

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