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
The Netherlands

In respect of:

The manufacture of administration sets.
Those aspects of Annex V related to securing and maintaining sterility of administration accessory products, withdrawal products, medical scrub brushes for mechanical cleaning, sponge stick for skin disinfection, surgical drapes, gowns and covers. Those aspects of Annex V related to the securing and maintaining of sterility in the assembly of procedure packs in accordance with Article 12 of the MDD.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

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