By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 648427**

Issued To: **Ivor Shaw Limited trading as**
Pennine Healthcare
300 City Gate
London Road
Derby
DE24 8WY
United Kingdom

In respect of:

Those aspects of Annex V concerned with securing and maintaining sterility in the manufacture of bile bags, connecting tubes, guedel airways, mucus extractors, rectal tubes, stomach tubes, urethral catheters, swabs, uterine dye dispensers / manipulators, surgical instrument covers, drapes, theatre gowns, surgical instrument tip cleaners, accessories for implanted port system.

Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs / systems in accordance with Article 12 of the Medical Devices Directive.

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

First Issued: **10 March 2016** Date: **05 April 2017** Expiry Date: **15 April 2022**

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