

# 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**

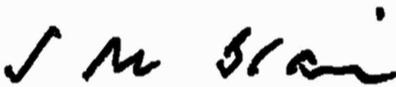
In respect of:

**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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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.