

EC Certificate - Production Quality Assurance

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

No. CE 642845
Issued To: medwork GmbH
Medworking 1
Höchstadt
91315
Germany

In respect of:

Those aspects of Annex V concerned with securing and maintaining the sterility in the manufacture of medical devices for flexible gastroenterological and surgical endoscopy, dilation balloons and instruments, sterile biliary and pancreatic duct endoprotheses and introducer sets, biliary drainage catheter sets, guidewires for the cannulation of the biliary duct and pancreas duct, and towels for use in endoscopic retrograde cholangiopancreatography procedures.

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: 2016-02-11

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Page 1 of 1

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.