



## EC Certificate - Production Quality Assurance

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

No.

**CE 01250** 

Issued To:

W.Söhngen GmbH Platter Strasse 84 D-65232 Taunusstein-V

D-65232 Taunusstein-Wehen

Germany

In respect of:

The manufacture of sterile emergency bags.
Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of sterile compress, bandage packs, sheets and dressings.

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):

Pietro Foschi - Strategic Delivery Director

First Issued: 12 March 1996

Date: 14 April 2015

Expiry Date: 31 March 2020

...making excellence a habit."

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.