

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-Wehen
Germany

In respect of:

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1996-03-12**

Date: **2020-03-19**

Expiry Date: **2024-05-26**

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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.

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Supplementary Information to CE 01250

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Number	Device Name	Intended purpose per IFU
Class Is		
SMDS7006	First Aid Dressings nonwoven (aluderm®, BambuCare®, DermaCare®, DERMOTEKT®, Dressing Sheets SO)	Not required for Class Is
SMDS7006	Gauze Dressings	Not required for Class Is
SMDS7006	Adhesive Dressings (aluderm®-aluplast Canula Plaster, aluderm®- aluplast sterile dressing)	Not required for Class Is
SMDS7006	Compression Bandages	Not required for Class Is

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Information and Contact: BSI, Bay Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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