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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

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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Supplementary Information to CE 01250

Issued To:

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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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