Continut trusa de replantare Soehngen

Nr. crt.	Articol	Cantitate (buc)
1	Punga replantare mica pentru mana	1
2	Folie izolanta pentru mana	1
3	Punga replantare mijlocie pentru brat	1
4	Folie izolanta pentru brat	1
5	Punga replantare mare pentru picior	1
6	Folie izolanta pentru picior	1
7	Punga gheata (14x20cm)	4
8	Bandaj special comprese	1
9	Compresa Aluderm 20x20cm	2
10	Compresa Aluderm 40x60cm	1
11	Bisturiu de unica folosinta	2
12	Foarfeca de haine 19 cm	1
13	Pensa Pean 14cm	1
14	Garou arterial DIN 13165	1
15	Set protectie (4 manusi)	2

bsi.

By Royal Charter

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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By Royal Charter

EC Certificate - Production Quality Assurance

Supplementary Information to CE 01250

Issued To:

W.Söhngen GmbH
Platter Strasse 84
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Germany

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

First Issued: **1996-03-12** Date: **2020-03-19** Expiry Date: **2024-05-26**

...making excellence a habit.®

SÖHNGEN
PROTECTING LIFE

Quality management
W. Söhngen GmbH

QUALITY MANAGEMENT

Quality management

W.Söhngen GmbH manufactures, distributes and imports first aid products, emergency medicine systems and products for qualified wound care.

We observe and respect European regulations and national laws, wherever they are authoritative and binding for our products. The medical devices we manufacture comply with the basic safety and performance requirements that apply to them, taking into consideration their intended purpose. A suitable conformity evaluation procedure has been carried out and a conformity declaration issued.

Any information required to identify the product and the manufacturer, and any information relevant to the user or, where applicable, third parties, concerning the safety and performance of the product is provided with our medical devices. We use internationally recognised symbols to identify our products wherever appropriate.

Our company has implemented a comprehensive quality management system in line with the requirements of EN ISO 13485 that meets both the requirements of the previous Directive 93/42/EEC on medical devices (MDD) dated 14 June 1993 and Regulation (EU) 2017/745 on medical devices (MDR) dated 05 April 2017.

SÖHNGEN® has held a certificate confirming compliance with the pertinent directive, CE 01250 issued by BSI, since 1996 for the manufacture of our sterile dressings as they are class Is medical devices and are therefore subject to regular monitoring. The validity of this certificate depends on the products and the applied QMS meeting the pertinent requirements set out in the directives, as proven by regular monitoring of the BSI. Our certificate confirming compliance with the pertinent directive, CE 01250, is valid until 26.05.2024.

A copy of this certificate is available on request.

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QUALITY MANAGEMENT

Medical Device Regulation – MDR
Regulation (EU) 2017/745

Regulation (EU) 2017/745 (Medical Device Regulation – MDR) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC (AIMDD) and 93/42/EEC (MDD) came into force on 25 May 2017. It was last amended by Regulation (EU) 2020/561 dated 23 April 2020. The MDR which came into force on 26 May 2021 is mandatory. The previous directives mentioned above are repealed and replaced by the MDR.

However, Article 120 (3) MDR specifies that a device classified as a class I(s) in accordance with Directive 93/42/EEC and for which a declaration of conformity was drawn up before the date of application and for which the conformity assessment procedure according to the MDR demands the involvement of a Notified Body or for which a valid certificate has been issued according to Directive 93/42/EEC, may continue to be placed on the market until 26 May 2024 as long as the device continues to comply with one of these directives and to the additional requirements set out in the MDR once the MDR comes into force.

On this basis, we confirm that the

class I medical devices we produce are still valid as of 26 May 2021.

- The products meet the requirements of the MDR
- An EU conformity declaration was issued as part of the conformity evaluation procedure to be applied according to the MDR.
- Products bear the CE marking
- Information on safe use is enclosed with the products
- The products are issued based on UDI-DI

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Quality management
W. Söhngen GmbH

QUALITY MANAGEMENT

Class Is medical devices

- We hold a valid MDD certificate from our Notified Body BSI NL (2797) for these products, valid until 26.05.2024.
- As part of the conformity evaluation procedure to be applied according to the MDD, an EU conformity declaration was issued before the MDR came into force
- Products bear the CE marking and the ID number of our Notified Body, 2797 = BSI NL
- Information on safe use is enclosed with the products
- The products continue to meet the requirements of Directive 93/42 EEC (MDD)
- The requirements of the MDR in view of monitoring after bringing to market, market monitoring, vigilance and registration of economic operators and products have been met

Aggregates

Filled containers such as cases, bags and cabinets are not medical devices in and of themselves, but aggregates. These are labelled with a LOT number and a date of manufacture which allow them to be traced. What characterises an aggregate is that the separate parts

- of which it is composed can, depending on how they are put together, be used
- separately and
- independently of each other
- for different purposes

The contents and parts of medical aggregates are often medical devices in their own right. These content parts have already been declared to comply in their own right, and are marked with MD and CE according to the specifications of the MDR (Regulation (EU) 2017/745 concerning medical devices) and the MPDG (Medical device implementation law) and Directive 93/42 EEC/MDD.

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