

W.Söhngen GmbH  
Platter Strasse 84  
65232 Taunusstein  
Germany

10<sup>th</sup> May 2024

## Notified Body Confirmation Letter

Reference: **EU2023-607/ 860008**

To whom it may concern,

### **Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

W.Söhngen GmbH  
Platter Strasse 84  
65232 Taunusstein  
Germany  
SRN Number: DE-MF-000026580

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

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BSI Group The Netherlands B.V.      bsigroup.com  
Say Building                              bsigroup.nl  
John M. Keynesplein 9, 1066 EP      T: +31 20 346 0780  
Amsterdam, The Netherlands

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Validity of this letter may be verified by writing to [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com)

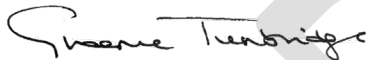


In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,



Graeme Tunbridge  
Senior Vice President, Medical Devices

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| <b>Device name or Basic UDI-DI (under MDR application)</b>       | <b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b> | <b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b> | <b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b> |
|--|--|---|---|
| aluderm Compress in various dimensions and packaging units       | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| aluderm Compress special in various versions and packaging units | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| aluderm Large dressing for abbraisons in various dimensions      | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| dermacare Compress in various dimensions and packaging units     | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| dermotekt Compress in various packaging units                    | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| aluderm Bandage pack in various dimensions and packaging units   | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| dermacare Bandage pack in various dimensions and packaging units | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| Dressing sheet SO DIN in various dimensions                      | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| aluderm Dressing sheet in various dimensions                     | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| dermacare Dressing sheet in various dimensions                   | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |
| Pressure bandage pack in various dimensions                      | Class I device placed on the market in sterile condition   | N/A   | Certificate CE 01250; NB2797  |

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|--|--|
| N/A   | N/A   | N/A  | N/A  |

**Confirmation Letter Revision History**

| Date       | Action        |
|------------|---------------|
| 2024/05/10 | Initial issue |

NB219A



## Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

|   |   |
|---|---|
| Manufacturer name                               | W.Söhngen GmbH                            |
| Manufacturer address and contact details        | Platter Straße 84<br>D- 65232 Taunusstein |
| Single Registration Number (SRN) (if available) | DE-MF-000026580                           |

|   |   |
|---|---|
| Authorised Representative name (if applicable)        | - |
| Authorised Representative address and contact details | - |
| Single Registration Number (SRN) (if available)       | - |

|   |  |
|---|--|
| Notified body name (if applicable)  | BSI Group The Netherlands B.V.<br><input type="checkbox"/> See attached schedule |
| Notified body number (if applicable)  | 2797<br><input type="checkbox"/> See attached schedule                           |
| Directive Certificate number(s) to which this confirmation is made (if applicable)                                    | CE01250<br><input type="checkbox"/> See attached schedule                        |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | 26.05.2024<br><input type="checkbox"/> See attached schedule                     |
| End date of extended validity/transition period   | 31.12.2028<br><input type="checkbox"/> See attached schedule                     |

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

*Choose applicable statements:*

Expired *before* 20 March 2023:

- Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

*Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:*

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Expired/expires *after* 20 March 2023:

*Choose one applicable statement:*

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

*Choose one applicable statement:*

A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

A QMS in accordance with Article 10(9) MDR is in place.

A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

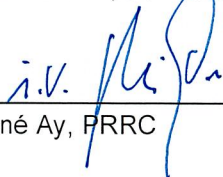
- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

W.Söhngen GmbH Postfach 1554 D-65223 Taunusstein

**Signed for and on behalf of the manufacturer:**

W.Söhngen GmbH

Taunusstein, den 26.02.2024

  
\_\_\_\_\_  
René Ay, PRRC

W.Söhngen GmbH

Réné Ay

Platter Straße 84

D-65232 Taunusstein

[ray@soehngen.com](mailto:ray@soehngen.com)

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W.Söhngen GmbH  
Erste Hilfe • Notfallmedizin

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Web: [www.soehngen.com](http://www.soehngen.com)

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SWIFT-BIC: NOLADE2H

Wiesbadener Volksbank  
IBAN: DE09 5109 0000 0071 0474 07  
SWIFT-BIC: WIBADE5W

Seite 4 von 7  
Geschäftsführer:  
Andreas Harms

Sitz der Gesellschaft: D-65232 Taunusstein  
HRB 16008, Amtsgericht Wiesbaden

Finanzamt Wiesbaden 040 225 81036  
USt.-Ident-Nr.: DE 325 337 848  
WEEE-Reg.-Nr.: DE 33612735

### Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s)<br>(e.g., device name, family/group name, device model or catalogue number)              | Directive Certificate number(s) to which this confirmation is made<br>(if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity<br>(if applicable) | Notified Body name and number that issued the Directive Certificate<br>(if applicable) | Notified Body name and number where the MDR application was lodged/contract signed<br>(if applicable) | End date of extended validity / transition period | Substitute Device(s)<br>(if applicable) |
|--|---|--|--|---|---|---|
| <b>SMDS7006</b><br><b>First Aid Dressings nonwoven (aluderm®, BambuCare®, DermaCare®, DERMOTEKT®, Dressing Sheet SO)</b> |   |  |  |   |   |   |
| aluderm Compress in various dimensions and packaging units   | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B.V.<br>2797  | BSI Group<br>The Netherlands B.V.<br>2797   | 31.12.2028  |   |
| aluderm Compress special in various versions and packaging units   | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B.V.<br>2797  | BSI Group<br>The Netherlands B.V.<br>2797   | 31.12.2028  |   |
| aluderm Large dressing for abrasions in various dimensions   | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B.V.<br>2797  | BSI Group<br>The Netherlands B.V.<br>2797   | 31.12.2028  |   |

| Identification of the device(s)<br>(e.g., device name, family/group name, device model or catalogue number) | Directive Certificate number(s) to which this confirmation is made<br>(if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity<br>(if applicable) | Notified Body name and number that issued the Directive Certificate<br>(if applicable) | Notified Body name and number where the MDR application was lodged/contract signed<br>(if applicable) | End date of extended validity / transition period | Substitute Device(s)<br>(if applicable) |
|---|---|--|--|---|---|---|
| dermacare Compress in various dimensions and packaging units  | CE01250   | 26.05.2024<br>(if applicable)  | BSI Group<br>The Netherlands B. V.<br>2797   | BSI Group<br>The Netherlands B. V.<br>2797  | 31.12.2028  |   |
| dermotekt Compress in various packaging units   | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B. V.<br>2797   | BSI Group<br>The Netherlands B. V.<br>2797  | 31.12.2028  |   |
| aluderm Bandage pack in various dimensions and packaging units  | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B. V.<br>2797   | BSI Group<br>The Netherlands B. V.<br>2797  | 31.12.2028  |   |
| dermacare Bandage pack in various dimensions and packaging units  | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B. V.<br>2797   | BSI Group<br>The Netherlands B. V.<br>2797  | 31.12.2028  |   |
| Dressing sheet SO DIN in various dimensions   | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B. V.<br>2797   | BSI Group<br>The Netherlands B. V.<br>2797  | 31.12.2028  |   |
| aluderm Dressing sheet in various dimensions  | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B. V.<br>2797   | BSI Group<br>The Netherlands B. V.<br>2797  | 31.12.2028  |   |

| Identification of the device(s)<br>(e.g., device name, family/group name, device model or catalogue number) | Directive Certificate number(s) to which this confirmation is made<br>(if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity<br>(if applicable) | Notified Body name and number that issued the Directive Certificate<br>(if applicable) | Notified Body name and number where the MDR application was lodged/contract signed<br>(if applicable) | End date of extended validity / transition period | Substitute Device(s)<br>(if applicable) |
|---|---|--|--|---|---|---|
| dermacare Dressing sheet in various dimensions  | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B.V.<br>2797  | BSI Group<br>The Netherlands B.V.<br>2797   | 31.12.2028  |   |
| <b>SMDS7006 Compression Bandages</b>  |   |  |  |   |   |   |
| Pressure bandage pack in various dimensions   | CE01250   | 26.05.2024   | BSI Group<br>The Netherlands B.V.<br>2797  | BSI Group<br>The Netherlands B.V.<br>2797   | 31.12.2028  |   |

## EG-KONFORMITÄTSERKLÄRUNG

entsprechend den Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte geändert durch die Richtlinie 2007/47/EG

## EC DECLARATION OF CONFORMITY

according to the requirements of the council Directive 93/42/EEC concerning medical devices amended by Directive 2007/47/EC

Wir / we

**W.SÖHNGEN GMBH**  
Platter Str. 84  
D-65232 Taunusstein

erklären in alleiniger Verantwortung, dass das Produkt/ die Produkte gem. Anlage I der Produktgruppe

declare under our sole responsibility that the product(s) according to attachment I of the product group

### Druckverbandpäckchen steril

### Pressure Bandage Packs sterile

mit den einschlägigen Bestimmungen der EG-Richtlinie 93/42/EWG über Medizinprodukte vom 14. Juni 1993 geändert durch die Richtlinie 2007/47/EG übereinstimmt.

comply with the relevant provisions of the EC Directive 93/42/EEC on medical devices of 14 June 1993, as amended by Directive 2007/47/EC.

Das Konformitätsbewertungsverfahren nach **Anhang VII in Verbindung mit Anhang V** wurde durchgeführt.

The conformity assessment procedure according to **Annex VII in conjunction with Annex V** was carried out.

Die Herstellungsschritte im Zusammenhang mit der Sterilisation für diese Medizinprodukte, **Klasse I(s)**, unterliegen der Überwachung durch folgende Benannte Stelle:

The manufacturing steps related to sterilization for these medical devices, **class I(s)**, are subject to surveillance by the following Notified Body:

BSI Group The Netherlands B.V.  
Niederlande  
Kenn- Nummer: 2797

BSI Group The Netherlands B.V.  
Netherlands  
Notified Body Number: 2797

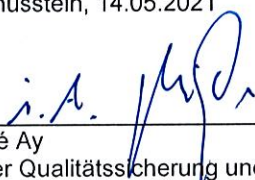
Zertifikat: CE 01250

Certificate: CE 01250

Konformitätserklärung gültig bis: 26.05.2024

Declaration of Conformity valid until: 26.05.2024

W.SÖHNGEN GMBH  
Taunusstein, 14.05.2021

  
René Ay  
Leiter Qualitätssicherung und Regulatory Affairs/  
Head of Quality Assurance and Regulatory Affairs

Seite 1 von 2

**EG-KONFORMITÄTSERKLÄRUNG**

entsprechend den Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte geändert durch die Richtlinie 2007/47/EG

**EC DECLARATION OF CONFORMITY**

according to the requirements of the council Directive 93/42/EEC concerning medical devices amended by Directive 2007/47/EC

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**Anlage I/ Attachment I**

Liste der Produkte zur Konformitätserklärung vom 14.05.2021  
für die Produktstammgruppe: **Druckverbandpäckchen steril**

List of products for the declaration of conformity dated 14.05.2021  
for the product master group: **Pressure Bandage Packs sterile**

| REF     | Produktname/<br>Product name  | Abmessung/<br>Dimension | Klasse/<br>Class | Regel/<br>Rule |
|---------|---|-------------------------|------------------|----------------|
| 1002010 | Druckverbandpäckchen, einzeln<br>Pressure bandage pack, single        | klein<br>small          | I (s)            | 4              |
| 1002001 | Druckverbandpäckchen, einzeln<br>Pressure bandage pack, single        |                         | I (s)            | 4              |
| 1050001 | Druckverbandpäckchen Kinder, einzeln<br>Pressure bandage pack, single |                         | I (s)            | 4              |

Seite 2 von 2

W.Söhngen GmbH  
Erste Hilfe • Notfallmedizin

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USt.-Ident-Nr.: DE 325 337 848  
WEEE-Reg.-Nr.: DE 33612735