

W.Söhngen GmbH
Platter Strasse 84
65232 Taunusstein
Germany

10th 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.

| | |
|--------------------------------|--------------------|
| 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 | |

Page 1 of 4

Validity of this letter may be verified by writing to Certificate.Verification@bsigroup.com

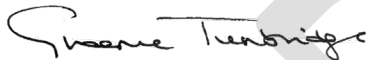


In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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:

| 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 |
|--|--|---|---|
| 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 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. <input type="checkbox"/> See attached schedule |
| Notified body number (if applicable) | 2797 <input type="checkbox"/> See attached schedule |
| Directive Certificate number(s) to which this confirmation is made (if applicable) | CE01250 <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 <input type="checkbox"/> See attached schedule |
| End date of extended validity/transition period | 31.12.2028 <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**

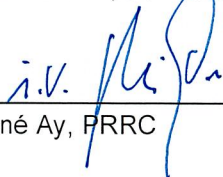
- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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

Telefon: +49 (0) 6128 8730

Schedule of Devices

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

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

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

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

EU-KONFORMITÄTSERKLÄRUNG
VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES ÜBER
MEDIZINPRODUKTE

EU DECLARATION OF CONFORMITY
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL
DEVICES

Wir / we
W.SÖHNGEN GMBH
Platter Str. 84
D-65232 Taunusstein
„SRN“ (Single Registration Number): DE-MF-000026580

erklären in alleiniger Verantwortung, dass die mit
CE gekennzeichneten Produkte gem. Anlage I der
Produktfamilie

BASIS-UDI: 42501088108J7

**Wundschnellverband Strips/ Fingerverbände,
unsteril
aluderm®-aluplast stab.**

Zweckbestimmung: zur Abdeckung von kleinen
Wunden

Klassifizierung: I
Regel: 4

auf die sich diese Erklärung bezieht, mit dem
Konformitätsbewertungsverfahren nach
**Artikel 19 in Verbindung mit den Anhängen
II und III**

gemäß den einschlägigen Bestimmungen der
VERORDNUNG (EU) 2017/745 DES
EUROPÄISCHEN PARLAMENTS UND DES
RATES vom 5. April 2017 über Medizinprodukte
übereinstimmt.

Angewandte Spezifikationen: N/A

Konformitätserklärung gültig bis: 31.03.2025

declare under our sole responsibility that the
products marked with CE according to Attachment I
of the product family

BASIC-UDI: 42501088108J7

**Adhesives for first aid strips/ finger plaster,
non-sterile
aluderm®-aluplast stab.**

Intended Purpose: for wound covering small
wounds

Classification: I
Rule: 4

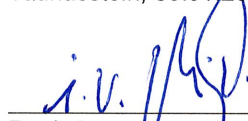
to which this declaration refers, corresponds with
the conformity assessment according to
Article 19 in conjunction with Annexes II and III

pursuant to the relevant provisions of REGULATION
(EU) 2017/745 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL of 5 April 2017 on medical
devices.

Common specifications applied: n/a

Declaration of Conformity valid until: 31.03.2025

W.SÖHNGEN GMBH
Taunusstein, 30.01.2024



Renè Ay
Leiter Qualitätsmanagement und Regulatory Affairs/
Head of Quality Management and Regulatory Affairs

EU-KONFORMITÄTSERKLÄRUNG
 VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES ÜBER
 MEDIZINPRODUKTE

EU DECLARATION OF CONFORMITY
 REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL
 DEVICES

Anlage I/ Attachement I
 Liste der Produkte zur Konformitätserklärung vom 30.01.2024
 für die Produktstammgruppe: **Wundschnellverband Strips/ Fingerverbände, unsteril,
 aluderm®-aluplast stab.**

List of products for the declaration of conformity dated 30.01.2024
 for the product master group: **Adhesives for first aid strips/ finger plaster, non-sterile,
 aluderm®-aluplast stab.**

| REF | Produktname/ Product name | Abmessung/ Dimension |
|----------|---|------------------------------|
| a1009121 | aluderm®-aluplast Pflaster-Strips, stab., einzeln aluderm®-aluplast Plaster strips stab., single | 1,9 x 7,2 cm 1,9 x 7,2 cm |
| a1009123 | aluderm®-aluplast Pflaster-Strips, stab., einzeln aluderm®-aluplast Plaster strips stab., single | 2,5 x 7,2 cm 2,5 x 7,2 cm |
| a1009127 | aluderm®-aluplast Fingerverband stab., einzeln aluderm®-aluplast finger plaster stab., single | 18 x 2 cm 18 x 2 cm |
| a1009129 | aluderm®-aluplast Fingerkuppenverband stab., einzeln aluderm®-aluplast Finger tip plaster stab., single | |
| 1009141 | aluderm®-aluplast Fingerkuppenverband stab., 10 Stück aluderm®-aluplast Finger tip plaster stab., 10 pcs | |
| 1009142 | aluderm®-aluplast Fingerkuppenverband stab., 50 Stück aluderm®-aluplast Finger tip plaster stab., 50 pcs | |
| 1009155 | aluderm®-aluplast Pflaster-Strips, stab., 10 Stück aluderm®-aluplast Plaster strips stab., 10 pcs | 1,9 x 7,2 cm 1,9 x 7,2 cm |
| 1009156 | aluderm®-aluplast Pflaster-Strips, stab., 50 Stück aluderm®-aluplast Plaster strips stab., 50 pcs | 1,9 x 7,2 cm 1,9 x 7,2 cm |
| 1009157 | aluderm®-aluplast Pflaster-Strips, stab., 10 Stück aluderm®-aluplast Plaster strips stab., 10 pcs | 2,5 x 7,2 cm 2,5 x 7,2 cm |
| 1009158 | aluderm®-aluplast Pflaster-Strips, stab., 50 Stück aluderm®-aluplast Plaster strips stab., 50 pcs | 2,5 x 7,2 cm 2,5 x 7,2 cm |
| 1009161 | aluderm®-aluplast Fingerverband stab., 10 Stück aluderm®-aluplast finger plaster stab., 10 pcs | 18 x 2 cm 18 x 2 cm |
| 1009162 | aluderm®-aluplast Fingerverband stab., 50 Stück aluderm®-aluplast finger plaster stab., 50 pcs | 18 x 2 cm 18 x 2 cm |