

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.

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Amsterdam, The Netherlands

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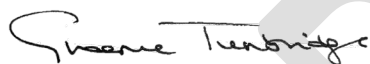
Validity of this letter may be verified by writing to Certificate.Verification@bsigroup.com

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

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. ☐ See attached schedule
Notified body number (if applicable)	2797 ☐ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE01250 ☐ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26.05.2024 ☐ See attached schedule
End date of extended validity/transition period	31.12.2028 ☐ 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.

➤ **Unclassified 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**

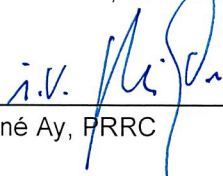
- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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

René 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	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	

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

Kompressen steril

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

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

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

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

Zertifikat: CE 01250

Konformitätserklärung gültig bis: 26.05.2024

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

Compresses sterile

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.

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

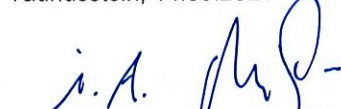
The manufacturing steps related to sterilization for these medical devices, **class I(s)**, are subject to surveillance by the following Notified Body:

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

Certificate: CE 01250

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 6

W.Söhngen GmbH
Erste Hilfe • Notfallmedizin

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Geschäftsführer:
Christoph Hirschmann

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

Finanzamt Wiesbaden 043 248 37524
USt-Ident-Nr.: DE 325 337 848
WEEE-Reg.-Nr.: DE 33612735

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

Anlage I/ Attachement I

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

List of products for the declaration of conformity dated 14.05.2021
for the product master group: **Compresses sterile**

REF	Produktname/ Product name	Abmessung/ Dimension	Klasse/ Class	Regel/ Rule
1003190	aluderm® aluface Gesichtsverband aluderm® aluface Face bandage		I (s)	4
1003208	aluderm® Komresse, einzeln aluderm® Compress, single	10 x 10 cm 10 x 10 cm	I (s)	4
1003209	aluderm® Komresse, einzeln aluderm® Compress, single	10 x 15 cm 10 x 15 cm	I (s)	4
1003210	aluderm® Komresse, einzeln aluderm® Compress, single	20 x 20 cm 20 x 20 cm	I (s)	4
1003211	aluderm® Komresse, einzeln aluderm® Compress, single	5 x 5 cm 5 x 5 cm	I (s)	4
1003213	aluderm® Komresse, einzeln aluderm® Compress, single	7,5 x 7,5 cm 7,5 x 7,5 cm	I (s)	4
1003214	aluderm® Lochkomresse, einzeln aluderm® perforated dressing pad, single	CH 8-30, 6 x 7 cm CH 8-30, 6 x 7 cm	I (s)	4
1003215	aluderm® Loch-/Schlitzkomresse, einzeln aluderm® perforated dressing pad, single	CH 32-50, 8 x 9 cm CH 32-50, 8 x 9 cm	I (s)	4
1003216	aluderm® alucap Kopfverband aluderm® alucap Head bandage		I (s)	4
1003217	aluderm® aluhand Handverband aluderm® aluhand Hand bandagej		I (s)	4
1003218	aluderm® aluarm Armverband aluderm® aluarm Arm bandage		I (s)	4
1003219	aluderm® aluleg Beinverband aluderm® aluleg Leg bandage		I (s)	4
1003220	aluderm® alufinger aluderm® alufinger Finger bandage		I (s)	4

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W.Söhngen GmbH
Erste Hilfe • Notfallmedizin

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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

Anlage I/ Attachement I

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

List of products for the declaration of conformity dated 14.05.2021
for the product master group: **Compresses sterile**

REF.	Produktname/ Product name	Abmessung/ Dimension	Klasse/ Class	Regel/ Rule
1003225	aluderm® Komresse 50 Stück in Steriltüte aluderm® Compress 50 pcs in sterile bag	5 x 5 cm 5 x 5 cm	I (s)	4
1003226	aluderm® Komresse 50 Stück in Steriltüte aluderm® Compress 50 pcs in sterile bag	7,5 x 7,5 cm 7,5 x 7,5 cm	I (s)	4
1003227	aluderm® Komresse 50 Stück in Steriltüte aluderm® Compress 50 pcs in sterile bag	10 x 10 cm 10 x 10 cm	I (s)	4
1003228	aluderm® Komresse 50 Stück in Steriltüte aluderm® Compress 50 pcs in sterile bag	10 x 15 cm 10 x 15 cm	I (s)	4
1003229	aluderm® Komresse 50 Stück in Steriltüte aluderm® Compress 50 pcs in sterile bag	20 x 20 cm 20 x 20 cm	I (s)	4
1003250	aluderm® Safe- Komresse, einzeln aluderm® Safe- Compress, single	30 x 40 cm 30 x 40 cm	I (s)	4
1003262	alulderm® Flächenverband Schürfwunden aluderm® Large dressing for abraisons	14 x 22 cm 14 x 22 cm	I (s)	4
1003263	alulderm® Flächenverband Schürfwunden aluderm® Large dressing for abraisons	21 x 30 cm 21 x 30 cm	I (s)	4
1003340	aluderm® Augenkomresse DuOcul, einzeln aluderm® Eye compress DuOcul, single		I (s)	4
1050140	aluderm® Kinder Ellenbogen- & Knieverband aluderm® Children elbow & kneebandage	6 cm breit 6 cm wide	I (s)	4
1050141	aluderm® Kinder Ellenboden- & Knieverband aluderm® Children elbow & kneebandage	8 cm breit 8 cm wide	I (s)	4
1050142	aluderm® Kinder Ellenboden- & Knieverband aluderm® Children elbow & kneebandage	10 cm breit 10 cm wide	I (s)	4

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Christoph Hirschmann

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

Finanzamt Wiesbaden 043 248 37524
USt.-Ident.Nr.: DE 325 337 848
WEEE-Reg.-Nr.: DE 33612735

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

Anlage I/ Attachement I

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

List of products for the declaration of conformity dated 14.05.2021
for the product master group: **Compresses sterile**

REF.	Produktname/ Product name	Abmessung/ Dimension	Klasse/ Class	Regel/ Rule
1050208	aluderm® Kinderkomresse, einzeln aluderm® Children Compress, single	4 x 6 cm 4 x 6 cm	I (s)	4
1050209	aluderm® Kinderkomresse, einzeln aluderm® Children Compress, single	6 x 6 cm 6 x 6 cm	I (s)	4
1050210	aluderm® Kinderkomresse, einzeln aluderm® Children Compress, single	8 x 6 cm 8 x 6 cm	I (s)	4
1050216	aluderm® Kinder-alucap Kopfverband aluderm® alucap Children head bandage	klein	I (s)	4
1050217	aluderm® Kinder-alucap Kopfverband aluderm® alucap children head bandage	groß	I (s)	4
1050262	aluderm® Kinder - Flächenverband Schürfwunden aluderm® Children-Large dressing for abaisons	14 x 22 cm 14 x 22 cm	I (s)	4
1050340	aluderm® Kinder- Augenkomresse DuOcul aluderm® Children- eye compress DuOcul		I (s)	4
ME10220	aluderm® alufinger versteppt aluderm® alufinger quilted		I (s)	4
CH10220	aluderm® alufinger versteppt, 100 Stück aluderm® alufinger quilted, 100 pcs		I (s)	4
KR03032	aluderm® Komresse, 30 Stück aluderm® Compress, 30 pcs	10 x 10 cm 10 x 10 cm	I (s)	4
KR03033	aluderm® Augenkomresse DuOcul, 10 Stück aluderm® Eye compress DuOcul, 10 pcs		I (s)	4

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

Anlage I/ Attachement I

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

List of products for the declaration of conformity dated 14.05.2021
for the product master group: **Compresses sterile**

REF.	Produktname/ Product name	Abmessung/ Dimension	Klasse/ Class	Regel/ Rule
ME10208	aluderm® Komresse, 100 Stück aluderm® Compress, 100 pcs	10 x 10 cm 10 x 10 cm	I (s)	4
ME10209	aluderm® Komresse, 100 Stück aluderm® Compress, 100 pcs	10 x 15 cm 10 x 15 cm	I (s)	4
ME10214	aluderm® Lochkomresse, 100 Stück aluderm® perforated dressing pad, 100 pcs	CH 8-30, 6 x 7 cm CH 8-30, 6 x 7 cm	I (s)	4
ME10216	aluderm® Loch-/Schlitzkomresse, 100 Stück aluderm® perforated dressing pad, 100 pcs	CH 32-50, 8 x 9 cm CH 32-50, 8 x 9 cm	I (s)	4
1003100	DermaCare® Komresse, einzeln DermaCare® Compress, single		I (s)	4
1003101	DermaCare® Komresse, einzeln DermaCare® Compress, single	30 x 40 cm 30 x 40 cm	I (s)	4
1003105	DermaCare® Komresse, einzeln DermaCare® Compress, single	10 x 10 cm 10 x 10 cm	I (s)	4
1003106	DermaCare® Komresse, einzeln DermaCare® Compress, single	10 x 15 cm 10 x 15 cm	I (s)	4
1003107	DermaCare® Komresse, einzeln DermaCare® Compress, single	20 x 20 cm 20 x 20 cm	I (s)	4
1003311	DermaCare® Komresse 50 Stück in Steriltüte DermaCare® Compress 50 pcs in sterile bag	10 x 10 cm 10 x 10 cm	I (s)	4
1050103	DermaCare® Kinder Komresse, einzeln DermaCare® Children- compress, single	4 x 6 cm 4 x 6 cm	I (s)	4
1050104	DermaCare® Kinderkomresse, einzeln DermaCare® Children- compress, single	6 x 6 cm 6 x 6 cm	I (s)	4

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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

Anlage I/ Attachement I

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

List of products for the declaration of conformity dated 14.05.2021
for the product master group: **Compresses sterile**

REF	Produktname/ Product name	Abmessung/ Dimension	Klasse/ Class	Regel/ Rule
1050105	DermaCare® Kinderkomresse, einzeln	8 x 6 cm	I (s)	4
	DermaCare® Children- compress, single	8 x 6 cm		
1003400	DERMOTEKT® Komresse, einzeln	10 x 10 cm	I (s)	4
	DERMOTEKT® Compress, single	10 x 10 cm		
1003401	DERMOTEKT® Komresse 2 Stück	10 x 10 cm	I (s)	4
	DERMOTEKT® Compress 2 pcs	10 x 10 cm		