W.Söhngen GmbH Postfach 1554 D-65223 Taunusstein

SÖHNGEN
PROTECTING LIFE

EU-KONFORMITÄTSERKLÄRUNG

VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES ÜBER MEDIZINPRODUKE

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

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

BASIS-UDI: 42501088126J9

BASIC-UDI: 42501088126J9

SIRIUS® Rettungsdecke

SIRIUS® Rescue Sheet

Zweckbestimmung: aluminiumbeschichtete Notfalldecke zum Schutz vor Kälte und Hitze und zur Vermeidung von Unterkühlung bei allen Notfallsituationen

Intended Purpose: aluminum-coated emergency blanket to protect against cold and heat and to prevent hypothermia in all emergency situations

Klassifizierung: I
Regel: 1

Classification: I
Rule: 1

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

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

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

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.

Angewandte Spezifikationen: N/A

Common specifications applied: n/a

Konformitätserklärung gültig bis: 31.03.2025

Declaration of Conformity valid until: 31.03.2025

W.SÖHNGEN GMBH
Taunusstein, 30.01.2024

i.V.

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

W.Söhngen GmbH
Erste Hilfe • Notfallmedizin

Platter Strasse 84
D-65232 Taunusstein

Postfach 1554
D-65223 Taunusstein

Tel.: 06128 873-0
Fax: 06128 840 84

Mail: info@soehngen.com
verkauf@soehngen.com
export@soehngen.com

Web: www.soehngen.com

Norddeutsche Landesbank, Hannover
IBAN: DE22 2505 0000 0151 8060 56
SWIFT-BIC: NOLADE2H

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

Geschäftsführer:
Christoph Hirschmann

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

W. Söhngen GmbH Postfach 1554 D-65223 Taunusstein

SÖHNGEN
PROTECTING LIFE

EU-KONFORMITÄTSERKLÄRUNG

VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES ÜBER MEDIZINPRODUKE

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: **SIRIUS® Rettungsdecke**

List of products for the declaration of conformity dated 30.01.2024
for the product master group: **SIRIUS® Rescue Sheet**

REF	Produktname/ Product name	Abmessung/ Dimension
0701001	SIRIUS® Rettungsdecke, einzeln	210 x 160 cm
	SIRIUS® Rescue Sheet, single	210 x 160 cm
1050040	SIRIUS® Rettungsdecke, einzeln, VPE 200 Stück	210 x 160 cm
	SIRIUS® Rescue Sheet, single, PU 200 pcs	210 x 160 cm
0701020	SIRIUS® Rettungsdecke, einzeln	160 x 120 cm
	SIRIUS® Rescue Sheet, single	160 x 120 cm
0702005	Super SIRIUS® Extra Rettungs- und Allzweckdecke, einzeln	200 x 150 cm
	Super SIRIUS® Extra Rescue and All-Purpose Sheet, single	200 x 150 cm
0750020	SIRIUS® Rettungsdecke KInder, einzeln	160 x 120 cm
	SIRIUS® Rescue Sheet Children, single	160 x 120 cm
DE07010	SIRIUS® Rettungsdecke, 100 Stück	210 x 160 cm
	SIRIUS® Rescue Sheet, 100 pcs	210 x 160 cm
EI07001	SIRIUS® Rettungsdecke gerollt, einzeln	220 x 160 cm
	SIRIUS® Rescue Sheet rolled, single	220 x 160 cm
SA07001	SIRIUS® Rettungsdecke, einzeln	210 x 160 cm
	SIRIUS® Rescue Sheet, single	210 x 160 cm

W. Söhngen GmbH
Erste Hilfe • Notfallmedizin

Platter Strasse 84
D-65232 Taunusstein

Postfach 1554
D-65223 Taunusstein

Tel.: 06128 873-0
Fax: 06128 840 84

Mail: info@soehngen.com
verkauf@soehngen.com
export@soehngen.com

Web: www.soehngen.com

Norddeutsche Landesbank, Hannover
IBAN: DE22 2505 0000 0151 8060 56
SWIFT-BIC: NOLADE2H

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

Geschäftsführer:
Christoph Hirschmann

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

W.Söhngen GmbH Postfach 1554 D-65223 Taunusstein

SÖHNGEN
PROTECTING LIFE

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 Nehterlands 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

W.Söhngen GmbH
Erste Hilfe • Notfallmedizin

Platter Strasse 84
D-65232 Taunusstein

Postfach 1554
D-65223 Taunusstein

Tel.: 06128 873-0
Fax: 06128 840 84

Mail: info@soehngen.com
verkauf@soehngen.com
export@soehngen.com

Web: www.soehngen.com

Norddeutsche Landesbank, Hannover
IBAN: DE22 2505 0000 0151 8060 56
SWIFT-BIC: NOLADE2H

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

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

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.

W.Söhngen GmbH
Erste Hilfe • Notfallmedizin

Platter Strasse 84
D-65232 Taunusstein

Postfach 1554
D-65223 Taunusstein

Tel.: 06128 873-0
Fax: 06128 840 84

Mail: info@soehngen.com
verkauf@soehngen.com
export@soehngen.com

Web: www.soehngen.com

Norddeutsche Landesbank, Hannover
IBAN: DE22 2505 0000 0151 8060 56
SWIFT-BIC: NOLADE2H

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

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

☒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
Erste Hilfe • Notfallmedizin

Platter Strasse 84
D-65232 Taunusstein

Postfach 1554
D-65223 Taunusstein

Tel.: 06128 873-0
Fax: 06128 840 84

Mail: info@soehngen.com
verkauf@soehngen.com
export@soehngen.com

Web: www.soehngen.com

Norddeutsche Landesbank, Hannover
IBAN: DE22 2505 0000 0151 8060 56
SWIFT-BIC: NOLADE2H

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

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

W.Söhngen GmbH Postfach 1554 D-65223 Taunusstein

Signed for and on behalf of the manufacturer:

W.Söhngen GmbH

Taunusstein, den 26.02.2024

i.V.

Réné Ay, PRRC

W.Söhngen GmbH
Réné Ay
Platter Straße 84
D-65232 Taunusstein
ray@soehngen.com
Telefon: +49 (0) 6128 8730

W.Söhngen GmbH
Erste Hilfe • Notfallmedizin

Platter Strasse 84
D-65232 Taunusstein

Postfach 1554
D-65223 Taunusstein

Tel.: 06128 873-0
Fax: 06128 840 84

Mail: info@soehngen.com
verkauf@soehngen.com
export@soehngen.com

Web: www.soehngen.com

Norddeutsche Landesbank, Hannover
IBAN: DE22 2505 0000 0151 8060 56
SWIFT-BIC: NOLADE2H

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

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

SCHNGEN
PROTECTING LIFE

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 abbraisions 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	

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.

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