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TÜV SÜD Product Service GmbH· · Germany

Livingstone International Pty Ltd
Suite 1, level 9, Bulding 3, 189 O'riordan Street
Mascot NSW 2020
AUSTRALIA

Your reference/letter of	Our reference	Email	Fax extension	Date	Page
71749	SIN_Living-stone_MDREXT_2024-rev00	medical_devices@tuvsud.com	-	2024-08-28	1 of 10

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 071749 0035 Rev. 00

Reference: SIN_Livingstone_MDREXT_2024-rev00

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: AU-MF-000030899

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 TÜV SÜD Product Service GmbH 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 TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CL 071749 0035

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-08-28

TÜV SÜD Product Service GmbH
Medical and Health Services

Ng Pui Yian, Amelia
Digitally signed by Ng Pui Yian, Amelia
Date: 2024.08.28 17:47:21 +08'00'

Ng Pui Yian, Amelia
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

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Franziska Eckert
2024.08.28 11:54:57 +02'00'

Franziska Eckert
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
Device 1 Livingstone Medicine Measure Cup **Art. Ref:** MEA30B **Basic UDI-DI:** ++G384MEATY	☒ Class I devices with measuring function	☒ N/A	☒ Certification as follows: Certificate: G2M 071749 0031 Rev 00 NB: 0123
Device 2 Livingstone Sterile Gauze Swabs **Art. Ref:** GSS5x1-100, GSS1X2-50, GSS1X3-50, GSS5X1-100, GSS7X1-100, GSS7X3-100 **Basic UDI-DI:** ++G384GSSVG	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 3 Livingstone Eye Pad Wound Dressing **Art. Ref:** EPX1X1L **Basic UDI-DI:** ++G384EPXV7	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 4 Nema Adhesive island Dressing with Non-Adherent Pad **Art. Ref:** LN250X082, LN180X082, LN082X060 LN075X050 LN120X082 **Basic UDI-DI:** ++G384LNCG	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 5 Livingstone Adhesive Fabric First Aid Roll with Pad **Art. Ref:** ASF601000 **Basic UDI-DI:** ++G384ASFTQ	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 6 Livingstone Superior Adhesive Recyclable Plastic Strips **Art. Ref:** ASP7219025N, ASP7219100, ASP7219100N **Basic UDI-DI:** ++G384ASPUC	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 7 Livingstone Adhesive Joint Knuckle Dressing **Art. Ref:** ASNWJS, ASNWJM **Basic UDI-DI:** ++G384ASNWJ7Z	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 8 Livingstone Adhesive Round Spot Plaster **Art. Ref:** ASP23N **Basic UDI-DI:** ++G384ASPUC	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 9 Livingstone Adhesive Joint Finger Dressing **Art. Ref:** ASNWF **Basic UDI-DI:** ++G384ASNWF7R	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 10 Livingstone Blue X-Ray Metal Detectable Adhesive Strips with Pad **Art. Ref:** ASPBLUE7318 **Basic UDI-DI:** ++G384ASPBLUE4P	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 11 Aqua-Liv Transparent Waterproof First Aid Adhesive Strips **Art. Ref** AQUA **Basic UDI-DI:** ++G384AQUAEN	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 12 Livingstone Butterfly Wound Closure **Art. Ref** BTRCLSN **Basic UDI-DI:** ++G384BTRCLSN6W	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 13 Livingstone Cotton Tip Applicator **Art. Ref:** CTAST75DP5A, CTASTW15X1N, CTASTW7X5 **Basic UDI-DI:** ++G384CTAST75	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 14 Livingstone Biodegradable Wooden Tongue Depressor **Art. Ref:** TDWX100 **Basic UDI-DI:** ++G384TDWXJE	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 15 Prone Non-Adherent Absorbent Dressing **Art. Ref:** LP100X100 LP100X200 LPL075X050 LPL075X100 LPL075X075 LPL075X200 LPL075X075 LP050X050 **Basic UDI-DI:** ++G384LPCL	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 16 Livingstone Cotton Ball **Art. Ref:** CTNBLX05 **Basic UDI-DI:** ++G384CTNBLX64	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 17 Universal Vaginal Speculum **Art. Ref:** SPECUCS_-200, SPECUCL-140, SPECUCL, SPECUCL-200 **Basic UDI-DI:** ++G384SPECUAX	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 18 Livingstone Basic Wound Dressing Pack **Art. Ref:** DRSPKB-162 **Basic UDI-DI:** ++G384DRSPKB7M	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123
Device 19 Urine Bag **Art. Ref:** UDB2000ML	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G2S 071749 0029 Rev.00 NB: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
UDBL500 **Basic UDI-DI:** ++G384UDBV7			
Device 20 Livingstone Dressing Scissors and Tweezer Forceps **Art. Ref:** SUTRMV **Basic UDI-DI:** ++G384SUTXL	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123
Device 21 Livingstone Hypodermic Needle **Art. Ref:** DN18GX1.0LV DN18GX1.5LV DN19GX1.0LV DN19GX1.5LV DN20GX1.0LV DN20GX1.5LV DN21GX1.0LV DN21GX1.25LV DN21GX1.5LV DN22GX0.75LV DN22GX1.0LV DN23GX0.75LV DN23GX1.0LV DN23GX1.25LV DN25GX0.6LV DN25GX1.0LV DN26GX0.5LV DN27GX0.5LV **Basic UDI-DI:** ++G384DNBQ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123
Device 22 Livingstone Syringe **Art. Ref:** DSL001MLS DSL001MLSC DSL003MLL DSL003MLLC DSL003MLS	☒ Class I devices in sterile condition ☒ Class I devices with measuring function	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
DSL003MLSC DSL005MLL DSL005MLS DSL010MLS DSL010MLSC DSL020MLES DSL020MLESC DSL050MLLC DSL060MLC DSL060MLES DSL060MLESC **Basic UDI-DI:** ++G384DSLUK			
Device 23 Livingstone plastic lancet **Art. Ref:** JPBLCT04 JPBLCT01 JPBLCT03 JPBLCT06 JPBLCT08 **Basic UDI-DI:** ++G384JPBLCT5E	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123
Device 24 Livingstone Surgical Scalpel Blade **Art. Ref:** SBLDCL10 SBLDCL11 SBLDCL15 SBLDCL12 SBLDCL24 SBLDCL26 SBLDCL25 **Basic UDI-DI:** ++G384SBLDCL4P	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123
Device 25 Livingstone Disposable Scalpel **Art. Ref:** SCP10 SCP11 SCP12	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
SCP15 SCP20 SCP21 SCP22 SCP24 **Basic UDI-DI:** ++G384SCPVN			
Device 26 Skin Shield Biodegradable Latex Surgical Gloves **Art. Ref:** GLVLTXS60PFM GLVLTXS60UM GLVLTXS65PFM GLVLTXS65UM GLVLTXS70PFM GLVLTXS70UM GLVLTXS75PFM GLVLTXS75UM GLVLTXS80PFM GLVLTXS80UM GLVLTXS85PFM GLVLTXS85UM **Basic UDI-DI:** ++G384GLVLTXSBP	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123
Device 27 Livingstone Digital Clinical Thermometer **Art. Ref:** CTSBDIGIME **Basic UDI-DI:** ++G384CTSUX	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123
Device 28 Livingstone Nebuliser Compressor **Art. Ref:** NEBLIVN **Basic UDI-DI:** ++G384NEBLEJ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 29 Livingstone Infrared Ear Thermometer **Art. Ref:** THRMET100A **Basic UDI-DI:** ++G384THRMETAK	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123
Device 30 Livingstone Oxygen Mask **Art. Ref:** OXYMSKADTB OXYMSKCHTB **Basic UDI-DI:** ++G384OXYMSKGB	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123
Device 31 Livingstone First Aid Kit **Art. Ref:** FAKCONBOAT **Basic UDI-DI:** ++G384FAKT5	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2 071749 0030 Rev.00 NB: 0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-08-28	SIN_Livingstone_MDREXT_2024-rev00	Initial issue