ATTESTATION / *CERTIFICATE* **N° 35913 rev. 3**

Délivrée à Paris le 22 mai 2021

Issued in Paris on May 22nd, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

Welch Allyn, Inc.

4341 State Street Road

Skaneateles Falls, NY 13153 UNITED STATES

Catégorie du(des) dispositif(s) / *Device(s) category*

Equipement et logiciel électrocardiographiques de diagnostic et de surveillance (multi-paramètres)

Electrocardiographic diagnostic and monitoring (multi-parameter) hardware and software

Voir document complémentaire GMED / See GMED additional document

n° 38602

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T001108, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T001108, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **May 22nd, 2021 (included)**

Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED SAS GMED SAS GMED GROUPE LNE

DocuSigned by: Beatrice Lys EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

GMED_b2p3_new2020-V0-04-

GMED - 35913 rev. 3
Modifie le certificat 35913-2

Délivré à Paris le 22/05/2021
Issued in Paris on 05/22/2021

Ce document complémentaire GMED n° 38602 rev. 0 atteste de la validité du certificat CE n° 35913 rev. 3 au regard des informations listées ci-dessous.

This GMED additional document N° 38602 rev. 0 attests to the validity of CE certificate n° 35913 rev. 3 with regard to the information listed below.

Fabricant / *Manufacturer:* **Welch Allyn, Inc.**
4341 State Street Road
Skaneateles Falls, NY 13153 UNITED STATES

Identification des dispositifs / *Identification of devices*

Description du Dispositif Médical *Medical Device Description*	**Référence Commerciale du Dispositif Médical** *Medical Device Commercial Reference Number*	**Classe du Dispositif Médical** *Medical Device Class*
ELECTROCARDIOGRAPH		
ELI 150c	ELI-150c- XXX-XXXXX X=A TO Z or 1 to 9	IIa
ELI 230	ELI230- XXX-XXXXX X=A TO Z	IIa
ELI 250c	ELI250c- XXX-XXXXX X=A TO Z	IIa
ELI 280	ELI280- XXX-XXXXX X=A TO Z	IIa

GMED 0459

GMED - 38602 rev. 0

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Description du Dispositif Médical *Medical Device Description*	**Référence Commerciale du Dispositif Médical** *Medical Device Commercial Reference Number*	**Classe du Dispositif Médical** *Medical Device Class*
ELI 380	ELI380-XYYZZ X= A TO Z Y = A TO Z Z= A TO Z or 1 to 9	IIa
RSCRIBE	RSCRIBE-XXX-XXXXX RSCRIBE LITE 11120-XXX-50 X= A to Z or 1 to 9	IIa
ELI PC/WAM PC Kit	41000-029-XX X= 0 to 9	IIa
HOLTER		
HSCRIBE/Burdick Vision Express	HSCRIBE-XXX-XXXXX HSERV-XXX-XXXXX X =A to Z BURV53H-X X=1 TO 9 HSCRIBWS-XXX-XXXXX X= A to Z or 1 to 9	IIa
H3+	H3PLUS-XXX-XXXXX X=A TO Z	IIa
H12+	H12PLUS-XXX-XXXXX X=A TO Z	IIa

GMED 0459

GMED - 38602 rev. 0

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Description du Dispositif Médical *Medical Device Description*	**Référence Commerciale du Dispositif Médical** *Medical Device Commercial Reference Number*	**Classe du Dispositif Médical** *Medical Device Class*
STRESS EXERCISES		
Q STRESS/XScribe	QS-XXX-XXXXX QR-XXX-XXXXX QSERV-XXX-XXXXX XSCRIBE-XXX-XXXXXX XR-XXX-XXXXX XSERV-XXX-XXXXX XScribe CP 41000-030-XX X=A to Z	IIa
TELEMETRY		
SURVEYOR CENTRAL SYSTEM	SCSYS- XXX-XXXXX X=A TO Z SCNODE- XXX-XXXXX SCAC-XXX-XXXXX SCREV- XXX-XXXXX X=A to Z	IIb
S4	S4-P-X X= A to Z S4-Q-XXX-XXX X = A to Z	IIb
PATIENT MONITOR		
S12/S19 PATIENT MONITOR	SUR12- XXX-XXXXX X=A TO Z SUR19- XXX-XXXXX X=A TO Z	IIb
ACQUISITION MODULES		
AM12, AM12Q, AM15	AM12 – 41000-032-XX; 9293-048-XX AM12Q – 9293-062-XX AM15E – 9293-063-XX	IIa
WAM, WAM PC	WAM - 30012-019-XX; 41000-31-XX; 41000-36-XX WAM PC - 30012-020-XX; 41000-029-XX	
AM12M	AM12M – 9293-065-XX	IIb
**Where X, Y, Z designates alpha characters denoting system configuration management codes important for post distribution servicing		

GMED 0459

GMED - 38602 rev. 0

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Sites couverts et Activités / *Locations and Activities*

Sites / *Locations*	**Activités** / *Activities*
Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 - USA	**Siège social** *Headquarters*
Welch Allyn, Inc. 7865 North 86th Street Milwaukee, WI 53224 - USA	**Conception** *Design*
Welch Allyn, Inc. 7900 North 86th Street Milwaukee, WI 53224 - USA	**Fabrication, Distribution et contrôle final** *Manufacturing, Distribution and Final Control*
Mortara Instrument Europe SRL Via G. di Vittorio 21/b3 40013 Castel Maggiore, Bologna - Italy	**Conception** *Design*

GMED	0459

GMED - 38602 rev. 0

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Legal Manufacturer Name: Welch Allyn Inc.

Legal Manufacturer Address: 4341 State Street Road, Skaneateles Falls, NY 13153 USA

Legal Manufacturer Single Registration Number (SRN): **US-MF-000013394**

Authorised Representative Name (if applicable): **Welch Allyn Limited**

Authorised Representative Address: **Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22 Ireland**

Authorised Representative Single Registration Number (SRN): **IE-AR-000000768**

Notified Body Name and Address: **GMED SAS**
1, rue Gaston Boissier
75015 PARIS, France

Notified Body Identification Number: 0459

MDD Certificate Number: **N° 35913 Rev. 3**

Original expiry date as indicated on the MDD Certificate prior to the extension of the validity: 26 May 2024

End date of extended validity/transition period [1]: 31 DECEMBER 2028

[1] according to Article 120 3a, as amended by Regulation (EU) 2023/607 (MDR).

+++ We, as the legal manufacturer declare under our sole responsibility:

- for the above listed **MDD Certificate** 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)** 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: +++

This declaration is made on the following basis:

1. The Directive 93/42/EEC (MDD) certificate(s) covering the listed devices was valid on 26 May 2021.
2. The device(s) continue to comply with Directive 93/42/EEC (MDD)
3. The device does not undergo a significant change in the design and intended purpose from 26 May 2021.

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

4. The device(s) do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

5. Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.

6. A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) is put in place by the manufacturer no later than 26 May 2024.

7. A formal application in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made to the notified body for the device(s) listed on this declaration or has been made in respect of a device intended to substitute a device listed on this declaration, no later than 26 May 2024 and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) no later than 26 September 2024.

Product/Trade Name and Product Code or REF. number: Refer to Appendix A

Device MDR Risk Class: IIa

Authorized Signatory:	
Name, Email Address and Title:	Joseph Olsavsky joseph_olsavsky@baxter.com Sr Director Regulatory Affairs
Name and Title	Joseph Olsavsky Sr Director Regulatory Affairs
Function	PRRC
Place of Issue:	Skaneateles Falls NY
Date of Issue:	09 MAY 2024
Signature:	JOSEPH OLSAVSKY JOSEPH OLSAVSKY (May 9, 2024 12:11 EDT)

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Appendix A: List of medical devices that are in compliance with the conditions listed in Article 120.3c

Product Code or REF number	Product or Trade Name
ELI 150C	ELI 150C
ELI 230	ELI 230
ELI 280	ELI 280
ELI 380	ELI 380
H3 PLUS	H3 PLUS
H12 PLUS	H12 PLUS
HSCRIBE	HScribe
QSTRESS	Q-Stress
XSCRIBE-6	X-Scribe

Please see Attachment A included with Appendix A-B-C for complete list of Product Codes

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Appendix B: Relationship Between MDD and MDR Codes

N/A

MDD product Code or REF number	MDD Product or Trade Name	MDR Product Code or REF Number (If the MDR device is a substitute[2] of the MDD device please include the word "substitute")	MDR Product or Trade Name	MDR Notified Body	MDR Legal Manufacturer

[2] MDR substitute device is a new version/model of the MDD device intended to replace the MDD device on the market which might differ from the MDD/legacy device by one or multiple of the non-exhaustive list of examples of changes here below

- additional, improved, updated, streamlined or removed functionality,
- improvement of manufacturability, efficiencies or reduced production cost,
- extended, modified, or reduced Intended Purpose,
- designed and manufactured utilizing new technologies or advanced components,
- being considered a step- or breakthrough-innovation, or

significant changes in design or intended purpose or other changes.

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

Welch Allyn, Inc.
4341 State Street Road
13153 SKANEATELES FALLS
USA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
93242	713302660	medical_devices@tuvsud.com		2024-04-10	1 of 15

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 093242 0013 Rev. 00

Reference: 713302660

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: US-MF-000013394

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=cert:CL 093242 0013 Rev. 00

The current revision of this Confirmation Letter is valid until 2024-09-26.

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-10

TÜV SÜD Product Service GmbH
Medical and Health Services

Riccardo Cottone
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Polyana GFV Heimes
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
Not applicable			

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
Device Name: SureTemp Plus 690 Thermometer **Device Name: SureTemp Plus 692 Thermometer** **BUDI: 0732094GMN901053F3**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 314505 MR2; NB# 0297 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device Name: SureTemp Plus Probe **BUDI: 0732094GMN901113EU**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 314505 MR2; NB# 0297 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: "DISCO" Ear Thermometer **BUDI: 0732094GMN901054F5**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1 314505 MR2; NB# 0297 or

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
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	Individual Article number: 06000-200; 06000-300	☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: ProBP 4000 Digital Blood Pressure Device **BUDI: 0732094GMN901198FW**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 34BXWT-2; 34XFHT-2; 34XFHT-4; 34XFHT-6; 34XFHT-B; 34XFST-2; 34XFST-4; 34XFST-6; 34XFST-B; 34XFWT-2; 34XFWT-4; 34XFWT-6; 34XFWT-B; 34XXHT-2; 34XXHT-4; 34XXHT-6; 34XXHT-B; 34XXST-2; 34XXST-4; 34XXST-6; 34XXST-B; 34XXWT-2; 34XXWT-4; 34XXWT-6; 34XXWT-B;	☒ Certification as follows: Certificate #1 314505 MR2; NB# 0297 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: ELI 280 Electrocardiograph **BUDI: 0732094GMN901132EY**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State

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
			had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: ELI 150C Electrocardiograph **BUDI: 0732094GMN901129FB**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: ELI 230 Electrocardiograph **BUDI: 0732094GMN901130EU**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: ELI 380 Electrocardiograph **BUDI: 0732094GMN901133F2**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or

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
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	Individual Article number:	☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: H12PLUS Holter Monitor **BUDI: 0732094GMN901141EZ**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: H3PLUS Holter Monitor **BUDI: 0732094GMN901142F3**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

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 Name: Qstress System **Device Name: Xscribe System** **BUDI: 0732094GMN901144F7**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: Hscribe **BUDI: 0732094GMN901143F5**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 35913 rev.3; NB# 0459 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: Welch Allyn Spot Vital Signs 4400 **BUDI: 0732094GMN901057FB**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 314505 MR2; NB# 0297 or ☐ N/A - Device did not require a Notified Body certificate under Directives

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
	☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments		or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: Welch Allyn Connex Spot Monitor **BUDI: 0732094GMN901058FD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1 314505 MR2; NB# 0297 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device Name: Welch Allyn "Seymour" Vital Signs Monitor **BUDI: 0732094GMN901188FT**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: 67MCEP-2; 67MCEP-4; 67MCEP-6; 67MCEP-B; 67MCEX-2; 67MCEX-4; 67MCEX-6; 67MCEX-B; 67MCTP-2; 67MCTP-4; 67MCTP-6; 67MCTP-B; 67MCTX-2; 67MCTX-4; 67MCTX-6; 67MCTX-B; 67MCXP-2; 67MCXP-4; 67MCXP-6; 67MCXP-B; 67MCXX-2; 67MCXX-4; 67MCXX-6; 67MCXX-B; 67MXDX-2 ; 67MXDX-4;	☒ Certification as follows: Certificate #1 314505 MR2; NB# 0297 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

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
		67MXDX-6; 67MXDX-B; 67NCDX-2; 67NCDX-4; 67NCDX-6; 67NCDX-B; 67NCEP-2; 67NCEP-4; 67NCEP-6; 67NCEP-B; 67NCEX-2; 67NCEX-4; 67NCEX-6; 67NCEX-B; 67NCTP-2; 67NCTP-4; 67NCTP-6; 67NCTP-B; 67NCTX-2; 67NCTX-4; 67NCTX-6; 67NCTX-B; 67NCXP-2; 67NCXP-4; 67NCXP-6; 67NCXP-B; 67NCXX-2; 67NCXX-4; 67NCXX-6; 67NCXX-B; 67NXDX-2; 67NXDX-4; 67NXDX-6; 67NXDX-B; 68MCEP-2; 68MCEP-4; 68MCEP-6; 68MCEP-B; 68MCEX-2; 68MCEX-4; 68MCEX-6; 68MCEX-B; 68MCTP-2; 68MCTP-4; 68MCTP-6; 68MCTP-B; 68MCTX-2; 68MCTX-4; 68MCTX-6; 68MCTX-B; 68MCXP-2; 68MCXP-4; 68MCXP-6; 68MCXP-B; 68MCXX-2; 68MCXX-4; 68MCXX-6; 68MCXX-7; 68MCXX-B; 68MXDX-2; 68MXDX-4; 68MXDX-6; 68MXDX-B; 68NCDX-2; 68NCDX-4; 68NCDX-6; 68NCDX-B; 68NCEP-2; 68NCEP-4; 68NCEP-6; 68NCEP-B; 68NCEX-2; 68NCEX-4; 68NCEX-6; 68NCEX-B; 68NCTP-2; 68NCTP-4; 68NCTP-6; 68NCTP-B; 68NCTX-2; 68NCTX-4; 68NCTX-6; 68NCTX-B; 68NCXP-2; 68NCXP-4; 68NCXP-6; 68NCXP-B; 68NCXX-2; 68NCXX-4; 68NCXX-6; 68NCXX-B; 68NXDX-2; 68NXDX-4; 68NXDX-6;	

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
		68NXDX-B; 84MTVE2-2; 84MTVE2-4; 84MTVE2-6; 84MTVE2-B; 84MTVEC-2; 84MTVEC-4; 84MTVEC-6; 84MTVEC-7; 84MTVEC-B; 84MTVEP-2; 84MTVEP-4; 84MTVEP-6; 84MTVEP-7; 84MTVEP-B; 84MTVEX-2; 84MTVEX-4; 84MTVEX-6; 84MTVEX-7; 84MTVEX-B; 84MTVX2-2 ; 84MTVX2-4 ; 84MTVX2-6 ; 84MTVX2-B ; 84MTVXC-2; 84MTVXC-4; 84MTVXC-6; 84MTVXC-7; 84MTVXC-B; 84MTVXP-2 ; 84MTVXP-4 ; 84MTVXP-6 ; 84MTVXP-7 ; 84MTVXP-B ; 84MTVXX-2; 84MTVXX-4; 84MTVXX-6; 84MTVXX-7; 84MTVXX; 84MXVEC-2; 84MXVEC-4; 84MXVEC-6; 84MXVEC-7; 84MXVEC-B; 84MXVEP-2; 84MXVEP-4; 84MXVEP-6; 84MXVEP-7; 84MXVEP-B; 84MXVEX-2; 84MXVEX-4; 84MXVEX-7; 84MXVEX-B; 84MXVXC-2; 84MXVXC-4; 84MXVXC-6; 84MXVXC-7; 84MXVXC-B; 84MXVXP-2; 84MXVXP-4; 84MXVXP-6; 84MXVXP-7; 84MXVXP-B; 84MXVXX-2; 84MXVXX-4; 84MXVXX-6; 84MXVXX-7; 84MXVXX-B; 84NTVEC-2 ; 84NTVEC-4 ; 84NTVEC-6 ; 84NTVEC-7 ; 84NTVEC-B ; 84NTVEP-2 ; 84NTVEP-4 ; 84NTVEP-6 ; 84NTVEP-7 ; 84NTVEP-B ; 84NTVEX-2 ; 84NTVEX-4 ; 84NTVEX-6 ; 84NTVEX-7 ; 84NTVEX-B ; 84NTVX2-2; 84NTVX2-4; 84NTVX2-6; 84NTVX2-B; 84NTVXC-2; 84NTVXC-4; 84NTVXC-6; 84NTVXC-7; 84NTVXC-B; 84NTVXP-2; 84NTVXP-4;	

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
		84NTVXP-6; 84NTVXP-7; 84NTVXP-B; 84NTVXX-2; 84NTVXX-4; 84NTVXX-6; 84NTVXX-7; 84NXVEC-2; 84NXVEC-4; 84NXVEC-6; 84NXVEC-7; 84NXVEC-B; 84NXVEP-2; 84NXVEP-4; 84NXVEP-6; 84NXVEP-7; 84NXVEP-B; 84NXVEX-2; 84NXVEX-4; 84NXVEX-6; 84NXVEX-7; 84NXVEX-B; 84NXVXC-2; 84NXVXC-4; 84NXVXC-6; 84NXVXC-7; 84NXVXC-B; 84NXVXP-2; 84NXVXP-4; 84NXVXP-6; 84NXVXP-7; 84NXVXP-B; 84NXVXX-2; 84NXVXX-4; 84NXVXX-6; 84NXVXX-7; 84NXVXX-B; 84XTVEC-2; 84XTVEC-4; 84XTVEC-6; 84XTVEC-7; 84XTVEC-B; 84XTVEP-2; 84XTVEP-4; 84XTVEP-6; 84XTVEP-7; 84XTVEP-B; 84XTVEX-2; 84XTVEX-4; 84XTVEX-6; 84XTVEX-7; 84XTVEX-B; 84XTVXC; 84XTVXC-4; 84XTVXC-6; 84XTVXC-7; 84XTVXC-B; 84XTVXP-2; 84XTVXP-4; 84XTVXP-6; 84XTVXP-7; 84XTVXP-B; 84XTVXX-2; 84XTVXX-4; 84XTVXX-6; 84XTVXX-7; 84XTVXX-B; 84XXVEC-2; 84XXVEC-4; 84XXVEC-6; 84XXVEC-7; 84XXVEC-B; 84XXVEP-2; 84XXVEP-4; 84XXVEP-6; 84XXVEP-7; 84XXVEP-B; 84XXVEX-2; 84XXVEX-4; 84XXVEX-6; 84XXVEX-7; 84XXVEX-B; 84XXVXC-2; 84XXVXC-4; 84XXVXC-6; 84XXVXC-7; 84XXVXC-B; 84XXVXP-2; 84XXVXP-4; 84XXVXP-6; 84XXVXP-7; 84XXVXP-B; 84XXVXX-2; 84XXVXX-4;	

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
		84XXVXX-6; 84XXVXX-7; 84XXVXX-B; 85MTVE3-2; 85MTVE3-4; 85MTVE3-6; 85MTVE3-7; 85MTVE3-B; 85MTVEC-2; 85MTVEC-4; 85MTVEC-6; 85MTVEC-7; 85MTVEC-B; 85MTVEP-2; 85MTVEP-4; 85MTVEP-6; 85MTVEP-7; 85MTVEP-B; 85MTVEX-2; 85MTVEX-4; 85MTVEX-6; 85MTVEX-7; 85MTVEX-B; 85MTVX3-2 ; 85MTVX3-4; 85MTVX3-6; 85MTVX3-B; 85MTVXC-2; 85MTVXC-4; 85MTVXC-6; 85MTVXC-7; 85MTVXC-B; 85MTVXP-2; 85MTVXP-4; 85MTVXP-6; 85MTVXP-7; 85MTVXP-B; 85MTVXX-2; 85MTVXX-4; 85MTVXX-6; 85MTVXX-7; 85MTVXX-B; 85MXVEC-2; 85MXVEC-4; 85MXVEC-6; 85MXVEC-7; 85MXVEC-B; 85MXVEP-2; 85MXVEP-4; 85MXVEP-6; 85MXVEP-7; 85MXVEP-B; 85MXVEX-2; 85MXVEX-4; 85MXVEX-6; 85MXVEX-7; 85MXVEX-B; 85MXVXC-2; 85MXVXC-4; 85MXVXC-6; 85MXVXC-7; 85MXVXC-B; 85MXVXP-2; 85MXVXP-4; 85MXVXP-6; 85MXVXP-7; 85MXVXP-B; 85MXVXX-2; 85MXVXX-4; 85MXVXX-6; 85MXVXX-7 ; 85MXVXX-B; 85NTVE3-2I; 85NTVE3-4I; 85NTVE3-6I; 85NTVE3-BI; 85NTVEC-2I; 85NTVEC-4I; 85NTVEC-6I; 85NTVEC-7I; 85NTVEC-BI; 85NTVEP-2I; 85NTVEP-4I; 85NTVEP-6I; 85NTVEP-7I; 85NTVEP-BI; 85NTVEX-2I; 85NTVEX-4I; 85NTVEX-6I; 85NTVEX-7I; 85NTVEX-BI; 85NTVX3-2; 85NTVX3-4; 85NTVX3-6;	

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
		85NTVX3-7; 85NTVX3-B; 85NTVXC-2; 85NTVXC-4; 85NTVXC-6; 85NTVXC-7; 85NTVXC-B; 85NTVXP-2; 85NTVXP-4; 85NTVXP-6; 85NTVXP-7; 85NTVXP-B; 85NTVXX-2; 85NTVXX-4; 85NTVXX-6; 85NTVXX-7; 85NTVXX-B; 85NXVEC-2; 85NXVEC-4; 85NXVEC-6; 85NXVEC-7; 85NXVEC-B; 85NXVEP-2; 85NXVEP-4; 85NXVEP-6; 85NXVEP-7; 85NXVEP-B; 85NXVEX-2; 85NXVEX-4; 85NXVEX-6; 85NXVEX-7; 85NXVEX-B; 85NXVXC-2; 85NXVXC-4; 85NXVXC-6; 85NXVXC-7; 85NXVXC-B; 85NXVXP-2; 85NXVXP-4; 85NXVXP-6; 85NXVXP-7;	

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/04/10	713302660	Initial issue