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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 021697 0017 Rev. 01

Manufacturer:

EnviteC - Wismar GmbH

Alter Holzhafen 18
23966 Wismar
GERMANY

Facility(ies):

EnviteC - Wismar GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Product Category(ies): Oxygen Saturation Sensors and Monitors,
Sensors and Control Units for Monitoring of
Respiratory Parameters and Gas Exchange,
Non-invasive Blood Pressure Equipment,
Temperature Sensors

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713172795

Valid from:

2020-02-17

Valid until:

2024-05-26

Date,

2020-02-17

Christoph Dicks
Head of Certification/Notified Body



Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 021697 0023 Rev. 00

Manufacturer:

Honeywell Healthcare Solutions GmbH

Alter Holzhafen 18
23966 Wismar
GERMANY

**This Confirmation Statement
is only valid in combination
with the following
EC Certificate (MDD):**

G1 021697 0017 Rev. 01

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer
data initiated 26 May 2021 or later.

The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for
placing devices on the market and putting into service apply.

Report No.:

713227588

Valid until:

2024-05-26

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2022-05-18

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 021697 0023 Rev. 00**Product Category(ies): Oxygen Saturation Sensors and Monitors,
Sensors and Control Units for Monitoring of
Respiratory Parameters and Gas Exchange,
Non-invasive Blood Pressure Equipment,
Temperature Sensor****Description of
Change:****Change of company name from:****EnviteC - Wismar GmbH****to****Honeywell Healthcare Solutions GmbH**



**Add value.
Inspire trust.**

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

Honeywell Healthcare Solutions GmbH
Alter Holzhafen 18
23966 Wismar

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
21697	713300514	medical_devices@tuvsud.com	N/A	2024-05-28	1 of 7

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 021697 0024 Rev. 01**

Reference: 713300514

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: DE-MF-000004924

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.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification body for medical Products
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747





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_021697_0024_Rev._01

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,

28th May 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'B. Schikowski'.

27.05.2024

Bernd Schikowski
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'Tunde Junaid'.

Tunde Junaid
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
Disposable Pulse Oximetry Sensors Basic UDI-DI: 4036616DSpO2SXR	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
Flow Sensors Basic UDI-DI: 4036616FlowH84	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
Flow Sensors Basic UDI-DI: 4036616FlowP8L	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
Oxygen Sensors INQOX Basic UDI-DI: 4036616INQOXVD	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
Oxygen Sensors MOX Basic UDI-DI: 4036616MOXCX	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
Oxygen Monitors Basic UDI-DI: 4036616O2MonUH	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
Oxygen Sensors Basic UDI-DI: 4036616OOM109MZ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
Oxygen Sensors Basic UDI-DI: 4036616OOMCK	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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
Reusable Pulse Oximetry Sensors Basic UDI-DI: 4036616RSpO2S5J	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
Pulse Oximetry Monitors Basic UDI-DI: 4036616SpO2MonMySBP	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
Pulse Oximetry Monitors Basic UDI-DI: 4036616SpO2MonOxER	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate: G1 021697 0017 Rev. 01; NB: 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



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: N/A

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

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/05/24	713300514	Initial issue
2024/05/28	713300514_CL-correction	Second issue (Rev. 01): Editorial corrections within table 1 including Device name.