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

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16100 KOTA BHARU, KELANTAN
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Udostępniono dla POLDENT w dniu 29/10/2024
Dokument jest własnością Arbonek Sp. z o.o.
ul. Brzostowska 22, 04-985 Warszawa
ZAKAZ UDOSTĘPNIENIA !!!

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
61155	713298433	medical_devices@tuvsud.com	N/A	2024-09-09	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 061155 0022 Rev. 01

Reference: 713298433

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: MY-MF-000023462

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For certificate validity see www.tuvsud.com/ps-cert?q=CL 061155 0022 Rev. 01

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

9th September 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

Signature: Nur Farrahin Md Zulkifli Farid (Sep 9, 2024 15:05 GMT+8)

Email: farrahin.zulkifli@tuvsud.com

Ms Nur Farrahin Zulkifli Farid
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Signature:

Email: tunde.junaid@tuvsud.com

Tunde Junaid
Application Reviewer

Udostępniono za GOLDEN w dniu 23/10/2024 Dokument jest własnością Abook Sp. z o.o. ul. Brzozowska 22, 04-985 Warszawa ZAKAZ UDOSTĘPNIENIA !!!

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
Sterile Latex Surgical Powdered Gloves **Basic UDI-DI:** **955507611000GF**	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1; G1 061155 0014 Rev. 02 NB 0123 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#
Sterile Latex Surgical Powder Free Gloves **Basic UDI-DI:** **955507611080H7**	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1; G1 061155 0014 Rev. 02 NB 0123 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#
Sterile Polychloroprene Surgical Powder Free Gloves **Basic UDI-DI:** **955507611160H6**	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1; G1 061155 0014 Rev. 02 NB 0123 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#
Sterile Polyisoprene Surgical Powder Free Gloves **Basic UDI-DI:** **955507611560HS**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1; G1 061155 0014 Rev. 02 NB 0123 or ☐ Evidence that a competent authority of a Member State had

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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 with measuring function ☐ Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Sterile Latex Examination Powder Free Gloves **Basic UDI-DI: 955507611680J5**	☐ 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	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1; G2S 061155 0015 Rev. 02 NB 0123 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#
Sterile Nitrile Examination Powder Free Gloves **Basic UDI-DI: 955507611720HQ**	☐ 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	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1; G2S 061155 0015 Rev. 02 NB 0123 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#
Sterile Latex Examination Powdered Gloves **Basic UDI-DI: 955507611760J4**	☐ 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	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1; G2S 061155 0015 Rev. 02 NB 0123 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#

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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 Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023/10/30	**713298433**	Initial issue
2024/09/09	**713298433**	Second Issue (Rev. 01) : Change of signature to electronic signature.

Udostępniono dla POLDENT w dniu 29/10/2024
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