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

Shenzhen Biocare Bio-Medical Equipment Co., Ltd. #16-1 Jinhui Road, Jinsha Community, Kengzi Sub-District Pingshan New District 518122 SHENZHEN PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
65758	713263772 BJ24089600- CL	medical_devices@tuvsud.com	N/A	2024-04-24	1 of 5

TÜV SÜD Product Service GmbH Confirmation Letter CL 065758 0007 Rev. 01

Reference: 713263772 | BJ24089600-CL

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: CN-MF-000005653

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 <u>not</u> 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 <u>www.tuvsud.com/ps-cert?q=CL 065758 0007 Rev. 01</u>

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

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

24th April 2024.

TÜV SÜD Product Service GmbH Medical and Health Services

Mr. Ming Zhang Conformity Assessment Responsible (CARE) TÜV SÜD Product Service GmbH Medical and Health Services

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 applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Refer- ence(s) of the devices under MDR application, and the NB Identifi- cation
Digital Electrocardiograph, 69376834iELJ	 □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb implantable (exempted) ⊠ Class IIa □ Class I devices in sterile condition 	⊠ N/A	 ☑ Certification as follows: Certificate No. G1 065758 0004 Rev.01; NB:CE0123
	 Class I devices with measuring function Class III implantable custom-made-device 		
Patient Monitor, 69376834iMM2	 Class III Class IIb implantable (non-exempted) Class IIb / Class IIb im- plantable (exempted) Class IIa Class I devices in sterile condition Class I devices with meas- uring function Class III implantable cus- tom-made-device 	⊠ N/A	⊠ Certification as follows: Certificate No. G1 065758 0004 Rev.01; NB:CE0123
Central Monitoring Sys- tem, 69376834PMK6	 □ 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	⊠ Certification as follows: Certificate No. G1 065758 0004 Rev.01; NB:CE0123
B-Ultrasonic Diagnostic Equipment, 69376834BUJC	 □ Class III □ Class IIb implantable (non-exempted) □ Class IIb / Class IIb implantable (exempted) ⊠ Class IIa □ Class I devices in sterile condition 	⊠ N/A	 ☑ Certification as follows: Certificate No. G1 065758 0004 Rev.01; NB:CE0123



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Refer- ence(s) of the devices under MDR application, and the NB Identifi- cation
	 Class I devices with measuring function Class III implantable custom-made-device 		
Doppler Fetal Heart Rate Detector, 69376834FM200QD	 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	 ☑ Certification as follows: Certificate No. G1 065758 0004 Rev.01; NB:CE0123
Fingertip Pulse Oximeter, 69376834BPJ2	 □ 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	 ☑ Certification as follows: Certificate No. G1 065758 0004 Rev.01; NB:CE0123
Fetal Monitor, 69376834FMJ8	 □ 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	⊠ Certification as follows: Certificate No. G1 065758 0004 Rev.01; NB:CE0123
Ambulatory Electrocardio- graphs, 69376834iHLQ	 Class III Class IIb implantable (non-exempted) Class IIb / Class IIb implantable (exempted) Class IIa Class IIa Class I devices in sterile condition 	⊠ N/A	⊠ Certification as follows: Certificate No. G1 065758 0004 Rev.01. NB:CE0123



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Refer- ence(s) of the devices under MDR application, and the NB Identifi- cation
	 Class I devices with measuring function Class III implantable custom-made-device 		

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-	MDR Device classification	If the MDR device is a substitute	MDD/AIMDD Certificate Refer-
DI (under MDR applica-	(as proposed by the manu-	device, identification of the corre-	ence(s) of the devices under
tion)	facturer and verified during	sponding MDD/AIMDD device	MDR application, and the NB
	application review)		Identification

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH in- ternal reference traceable to each ver- sion of the letter	Action
2024/04/19	713263772 BJ24089600-CL	Initial issue
2024/0424	713263772 BJ24089600-CL	Second Issue (Revision 1) : Certificate link on 1 st issue had problems so it had to be corrected