Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Bain Medical Equipment (Guangzhou) Co., Ltd.
No. 10, Juncheng Road, Eastern Area, Economic and Technological Development District,
510760 Guangzhou,
P.R. China

Contact

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Date March 15, 2024

Notified Body Confirmation Letter
Reference. : 10924232

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has 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 following manufacturer:

Bain Medical Equipment (Guangzhou) Co., Ltd.
No. 10, Juncheng Road, Eastern Area, Economic and Technological Development District,
510760 Guangzhou,
P.R. China
SRN Number (if available): CN-MF-000005196

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 the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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, by March 20, 2023 for the relevant devices.

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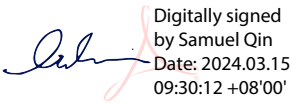
The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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)

On behalf of the Notified Body



Samuel Qin

Certification body

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage)**	**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**
Tubing Sets for Hemodialysis Basic UDI-DI: 6948082701181A6	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Tubing Sets for Hemodialysis Basic UDI-DI: 6948082701183AA	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Tubing Sets for Hemodialysis Basic UDI-DI: 6948082701182A8	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Hollow Fiber Dialyzer Basic UDI-DI: 6948082703313AD	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197
Hollow Fiber Dialyzer	Class IIb excluding Class IIb	N/A	Certificate # HD 1518511-1

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Basic UDI-DI: 6948082703312AB	implantable non-WET		NB #0197
Hollow Fiber Dialyzer Basic UDI-DI: 6948082703413AJ	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197
Hollow Fiber Dialyzer Basic UDI-DI: 6948082703412AG	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197
Hollow Fiber Dialyzer Basic UDI-DI: 6948082703323AG	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197
Hollow Fiber Dialyzer Basic UDI-DI: 6948082703322AE	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197
Hollow Fiber Dialyzer Basic UDI-DI: 6948082703423AM	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197
Hollow Fiber Dialyzer Basic UDI-DI: 6948082703422AK	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197
Disposable A.V. Fistula Needle Sets Basic UDI-DI: 69480827021319W	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Disposable A.V. Fistula Needle Sets Basic UDI-DI: 6948082702133A2	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Disposable A.V. Fistula Needle Sets Basic UDI-DI: 69480827021329Y	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Disposable A.V. Fistula Needle Sets (Safety Needle series) Basic UDI-DI: 6948082702151A4	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Disposable A.V. Fistula Needle Sets (Safety Needle series) Basic UDI-DI: 6948082702153A8	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Disposable A.V. Fistula Needle Sets	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
(Safety Needle series) Basic UDI-DI: 6948082702152A6			
Disposable A.V. Fistula Needle Sets (Dull Needle series) Basic UDI-DI: 69480827021419Z	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Disposable A.V. Fistula Needle Sets (Dull Needle series) Basic UDI-DI: 6948082702143A5	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Disposable A.V. Fistula Needle Sets (Dull Needle series) Basic UDI-DI: 6948082702142A3	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Fluid supplementary tubing sets for blood purification Basic UDI-DI: 6948082710181AA	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Tubing Sets for Blood Purification Basic UDI-DI: 6948082705181B2	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Drain Bags Basic UDI-DI: 6948082712181AQ	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 1518511-1 NB #0197
Disposable Hemodialysis Care Kits Basic UDI-DI: 6948082707581C4	Class I devices placed on the market in sterile condition	N/A	Certificate # HD 1518511-1 NB #0197
Disposable Hemodialysis Care Kits Basic UDI-DI: 6948082707681C9	Class IIa	N/A	Certificate # HD 1518511-1 NB #0197
Plasmafilters Basic UDI-DI: 6948082709383CC	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197
Hemodialysis Bicarbonate Basic UDI-DI: 6948082711464AY	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Hemodialysis Bicarbonate Basic UDI-DI: 6948082711774BJ	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 1518511-1 NB #0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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 at the pre-application stage)	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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-03-15	10924232	Initial issue