Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

B&E KOREA Co., Ltd.
995-16, Baran-ro
Jeongnam-myeon, Hwaseong-si
Gyeonggi-do, 18515
Republic of Korea

Contact

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Mail: medical-products@de.tuv.com

Date October 06, 2023

Notified Body Confirmation Letter
Reference. : B&E_MDR_CL_2023-10-06

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:

B&E KOREA Co., Ltd.
995-16, Baran-ro
Jeongnam-myeon, Hwaseong-si
Gyeonggi-do, 18515
Republic of Korea
SRN Number (if available): KR-MF-000030252

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.

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:

- 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

On behalf of the Notified Body

Michiaki Aihara
Certification body

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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
Dental etchant (Basic UDI-DI: 88000353B&EEtchantT7)	Class IIa	Not applicable.	NB 0197 (Registration No.: HD 60145041 0001)
Dental temporary cement (Basic UDI-DI: 88000353B&ETempCementBR)	Class IIa	Not applicable.	NB 0197 (Registration No.: HD 60145041 0001)
Dental composite resin (Basic UDI-DI: 88000353B&EComposite9T)	Class IIa	Not applicable.	NB 0197 (Registration No.: HD 60145041 0001)
Dental temporary filling materials (Basic UDI-DI: 88000353B&ETempFillSM)	Class IIa	Not applicable.	NB 0197 (Registration No.: HD 60145041 0001)
Orthodontic adhesives (Basic UDI-DI: 88000353B&EOrthoAd33)	Class IIa	Not applicable.	NB 0197 (Registration No.: HD 60145041 0001)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-10-06	B&E_MDR_CL_2023-10-06	Initial issue

Digitally signed by Benderschi Tamara
Date: 2024.01.18 12:40:57 EET
Reason: MoldSign Signature
Location: Moldova