TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60146609 0001

Report No.: 12031466 004

Manufacturer:
MARUCHI
2-208, Medical Industry Complex Bldg., 42-10
Taejanggongdan-gil
Wonju-si, Gangwon-do 26311
Republic of Korea

Products:
Root Canal Filling Materials
(see attachment for additional sites included)

Replaces Approval Registration No.: HD 60133341 0001

Expiry Date: 2023-07-12

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-03-23

Date: 2020-03-23

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland® III

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146609 0001
Report No.: 12031466 004

Manufacturer:
MARUCHI
2-208, Medical Industry Complex Bldg., 42-10
Taejanggongdan-gil
Wonju-si, Gangwon-do 26311
Republic of Korea

Site included:

MARUCHI Package&warehouse
4-205, Medical Industry Complex Bldg., 42-10,
Taejanggongdan-gil, Wonju-si, Gangwon-do, 26311,
Republic of Korea

MARUCHI R&D Center
502, 200, Gieopdosi-ro, Jijeong-myeon, Wonju-si,
Gangwon-do, 26354, Republic of Korea

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2020-03-23

M.Sc. M. Aihara

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

MARUCHI
101, Donghwagongdan-ro,
Munmak-eup, Wonju-si,
Gangwon-do, 26365
Republic of Korea

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date August 10, 2023

Application for: QMS

Certificate No.	: HD 60146609 0001
Requirement	: MDD Annex II excl. 4
Confirmation letter ID	: 2023-08-10_HD 60146609 0001
Report no.	: 156156170-40

To whom it may concern,

Update of information to Certificate no. HD 60146609 0001, issued on 2020-03-23

The change notifications received on 2022-08-12 and 2023-04-03 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notifications are not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Authorized European Representative change:

KTR Europe GmbH
Mergenthalerallee 77, 65760 Eschborn
Germany

Revised Manufacturer address:

Old Manufacturer address:

2-208, Medical Industry Complex Bldg., 42-10, Taejanggongdan-gil, Wonju-si, Gangwon-do, 26311, Republic of Korea

4-205, Medical Industry Complex Bldg., 42-10, Taejanggongdan-gil, Wonju-si, Gangwon-do, 26311, Republic of Korea

502, 503, 200, Gieopdosi-ro, Jijeong-myeon, Wonju-si, Gangwon-do, 26354, Republic of Korea

New Manufacturer address:
101, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365
Republic of Korea

Best regards,

Ning Chang

Ning N. C. Chang
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

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Business Stream Products
Certification Department

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26365, Republic of Korea

Contact

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Mail: medical-products@de.tuv.com

Date October 31, 2023

Notified Body Confirmation Letter
Reference. : MARUC_MDR_CL_2023-10-31

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:

MARUCHI
101, Donghwagongdan-ro, Munmak-eup
Wonju-si, Gangwon-do
26365, Republic of Korea
SRN Number (if available): KR-MF-000030192

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.

In the case of devices covered by certificates issued under 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 certificate expiry.

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

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

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90431 Nuremberg

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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
ENDOSEAL MTA (Basic UDI-DI: 08800071200000TZ)	Class IIa implantable, WET device	Not applicable.	NB 0197 (Registration No.: HD 60146609 0001)
SendoSeal MTA (Basic UDI-DI: 08800071200000TZ)	Class IIa implantable, WET device	Not applicable.	NB 0197 (Registration No.: HD 60146609 0001)
CleaniCal (Basic UDI-DI: 08800071200017UJ)	Class IIa	Not applicable.	NB 0197 (Registration No.: HD 60146609 0001)
ENDOCEM MTA PREMIXED REGULAR (Basic UDI-DI: 08800071200130UF)	Class IIa implantable, WET device	Not applicable.	NB 0197 (Registration No.: HD 60146609 0001)
White ENDOSEAL MTA (Basic UDI-DI: 08800071200093V2)	Class IIa implantable, WET device	Not applicable.	NB 0197 (Registration No.: HD 60146609 0001)
VDW.1SEAL (Basic UDI-DI: 08800071200093V2)	Class IIa implantable, WET device	Not applicable.	NB 0197 (Registration No.: HD 60146609 0001)
AH Plus Bioceramic Sealer (Basic UDI-DI: 08800071200093V2)	Class IIa implantable, WET device	Not applicable.	NB 0197 (Registration No.: HD 60146609 0001)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/10/31	MARUC_MDR_CL_2023-10-31	Initial issue