

EC DECLARATION OF CONFORMITY

Manufacturer: MARUCHI

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

European Representative: KTR Europe GmbH

Megenthalerallee 77, 65760, Eschborn, Germany

Notifies Body: TÜV Rheinland Product Safety GmbH

Tillystraße 2, 90431 Nürnberg, Germany (Notified Body no.: 0197)

COMMON NAME: ROOT CANAL FILLING MATERIAL

Model name	Item Reference	Description	GMDN Code
AH Plus® Bioceramic Sealer	BKTAHBS000000	AH Plus® Bioceramic Starter Kit	60510
	B00AHBS10003G	AH Plus® Bioceramic Syringe Refill	60510
	B00AHBS00DEMO	AH Plus® Bioceramic Demo Syringe – not for sale	60510
VDW.1Seal™ Bioceramic Sealer	M00V1SM10003G	VDW.1Seal™ Bioceramic Syringe Refill	60510
	MKTV1SM000000	VDW.1Seal™ Bioceramic Starter Kit	60510
	M00V1SMDEMO	VDW.1Seal™ Bioceramic Demo Syringe – not for sale	60510

CLASSIFICATION: Class IIa by Rule 8 of Annex IX,

Council Directive 93/42/EEC as amended by Directive 2007/47/EC

CONFORMITY ASSESSMENT ROUTE: Annex II (Clause 4 excluded),

Council Directive 93/42/EEC as amended by Directive 2007/47/EC and Annex IX

(Quality Management System), Regulation (EU) 2017/745

EMDN CODE: Q01010201

We hereby declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer. Therefore, we are exclusively responsible for the declaration of conformity.

Reason for EC Declaration of Conformity revision : Relocation of manufacturing facilities

We declare that the relocation of the manufacturing facilities does not directly affect the safety and performance of the above-mentioned products.

- Previous address : 2-208, Medical Industry Complex Bldg., 42-10, Taejanggongdan-gil, Wonju-si, Gangwon-do, 26311, Republic of Korea
- Changed address : 101, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365, Republic of Korea
- Date of relocation of the manufacturing facilities : 2023-08-10

STANDARDS APPLIED: EN ISO 20417:2021, EN 1641:2009, IEC 62366-1:2015, IEC 62366-2:2016, EN ISO 6876:2012, EN ISO 7405:2018, EN ISO 10993-1:2020, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-10:2021, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-23:2021, EN ISO 13485:2016, EN ISO 14971:2019, ISO TR 24971:2020, EN ISO 15223-1:2021, ISO 7000:2019, EN ISO 21531:2009, ISTA 2018

Certificate no.: HD 60146609 0001

Issue date: 2020-03-23

Expiry date: 2023-07-12

Product information (Lot number): KIYYMMDD



SIGNATURE:

Jang sung wook

President of MARUCHI

Gangwon-do, Korea

August 10, 2023