MARUCHI

101, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do,

Republic of Korea, 26365 tel:+82-33-734-0330 fax:+82-33-746-2804, http:www.endoland.com

2023/607/EU SELF-DECLARATION

To whom it may concern

We,

MARUCHI
101, Donghwagongdan-ro, Munmak-eup, Wonju-si,
Gangwon-do, 26365 Republic of Korea
+82-33-734-0330 / info@endocem.com

do hereby declare that the products listed in ANNEX I of this self-declaration are in scope of the European Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices by complying with the following requirements:

a) Devices continue to comply with Directive 93/42/EEC,

b) There are no significant changes in design and intended purpose,

c) Devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health,

d) No later than 26 May 2024, the manufacturer has put in a QMS in accordance with EU MDR,

e) No later than 26 May 2024, the manufacturer has lodged a formal application with a notified body, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with EU MDR.

Therefore, the EC Certificate(HD 60146609 0001) is considered as valid until the 31.12.2028

Yours Sincerely,

Wonju-si, 10/11/2023

_____

Sungwook Jang
CEO

101, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do,

Republic of Korea, 26365 tel:+82-33-734-0330 fax:+82-33-746-2804, http:www.endoland.com

ANNEX I – According to MDD Extension, the devices for the continued placing on the market

Notified Body	TÜV Rheinland Product Safety GmbH		
Date of Extension Agreement	March 8, 2023		
Expiration Date of Extension	December 31, 2028		
Standard(s)	MDD 93/42/EEC		
Agreement Scope(s)	Root Canal Filling Materials		
Extension Reason	To maintain the MDD Certificate while MDR Audit is not completed		
Contact Information of NB	+49 911 655-5225 / medical-products@de.tuv.com		
Contact Address of NB	Tillystraße 2, 90431 Nürnberg, Germany		
Device Name	1. ENDOSEAL MTA - SendoSeal MTA 2. ENDOCEM MTA PREMIXED REGULAR 3. White ENDOSEAL MTA - VDW.1SEAL - AH Plus Bioceramic Sealer	**MDR Classification**	Class IIa implantable, WET device
	4. CleaniCal		Class IIa
MDD Certificate Reference(s)	EC Certificate (HD 60146609 0001)		

Note : Certificate HD 60146609 0001 was originally expired on 12 July 2023 and now it is under the MDD certification Extension Agreement provided by TÜV Rheinland Product Safety GmbH in 8 Maruch 2023, the transition timeline that apply to the devices covered by this letter, subject to the munufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR(as amended by EU 2023/607), are 31 December 2028.