BioMTA

301, 175, Dasan-ro, Jung-gu, Seoul, Republic of Korea

Declaration of Conformity

Name of manufacturer: BioMTA
Address: 301, 175, Dasan-ro, Jung-gu, Seoul, Republic of Korea
Declares on our sole responsibility, that the Medical Devices:

Medical Device Name	Export Name	Classification	Legal Regulation According Council of Europe Medical Device Directive MDD93/42/EEC
Resin, Filling, Adhesive, Composit	OrthoMTA RetroMTA	IIa	Annex IX

Conformity assessment routine: MDD Annex V.3

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed, and it had been classified as Class Iia, in accordance Annex I, V and IX of the Europe Medical Device Directive 93/42/EEC.

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standard ISO 13485:2016.

The Declaration of Conformity is based on the EC Directives 93/42/EEC, Annex II (excluding section 4) under the supervision of Notified body, SZUTEST Uygunluk Değerlendirme A.Ş.

The above mentioned Declaration of Conformity is under BioMTA responsibility exclusively.

Date of issue: 25/05/2022

Place of issue: Seoul, Republic of Korea

Signature (of authorized person): _____

Typed name (of authorized person): Jun Sang, Yoo

Position/Title: President

Stamp/Seal: