

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: / **ChangZhou BoMedent Medical Technology Co., Ltd.**
No.9 Changyang Road, West Taihu Science and Technology
Industrial Park, Changzhou, 213000 Jiangsu, P.R. China

Trade mark:/



SRN of manufacturer:/

CN-MF-000010413

EC Authorized Representative:/

Caretechion GmbH
Niederrheinstr. 71,
40474 Duesseldorf, Germany
DE-AR-000005946

SRN:

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device:

Name of the medical device: /

Endodontic obturation devices
Model: eFiller

Product code:/

EMDN code: Z121101

Intended purpose: /

It is used for root canal filling during root canal treatment.

Basic UDI-DI:/

697107537eFillerYG

of class: /

Rule 12, sub-clause 1, no indent, Class IIa
According to annex VIII of Regulation (EU) 2017/745 /

Conformity assessment procedure:/

Annex IX Chapter I, Section 2 and 3
According to Para.1 of Article 52(6) of Regulation (EU) 2017/745

Notified Body: /

TÜV Rheinland LGA Products GmbH,
Tillystraße 2, 90431, Nürnberg, Germany

NB Identification number: /

CE 0197

CS reference: /

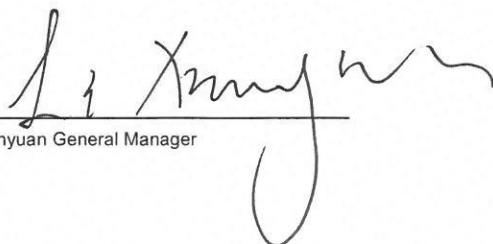
None

According to annex VIII of Regulation (EU) 2017/745 /

We, the manufacturer, hereby declare under our sole responsibility that the abovementioned products meet the provisions of the Medical Device Regulation (EU) 2017/745. All supporting documents are retained under the premises of the manufacturer.

CHANGZHOU, 2024-5-23

Ort, Datum / Place, date /


Li Xinyuan General Manager