EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: /	**ChangZhou BoMedent Medical Technology Co., Ltd.** **No.9 Changyang Road, West Taihu Science and Techology Industrial Park, Changzhou, 213000 Jiangsu, P.R. China**
Trade mark:/	Bondent 博恩集团
SRN of manufacturer:/	**CN-MF-000010413**
EC Authorized Representative:/	**Caretechion GmbH** **Niederrheinstr. 71,** **40474 Duesseldorf, Germany**
SRN:	**DE-AR-000005946**

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: eHeater**
Product code:/	**EMDN code: Z121101**
Intended purpose: /	**It is used to soften and/or cut off the gutta percha point outside the mouth for root canal filling.**
Basic UDI-DI:/	**697107537eHeaterWR**
of class: /	**Rule 9, 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