


## 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:/  **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**

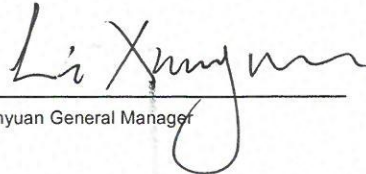
CS reference: / **None**

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