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: /	**Dental Root Canal Measuring and Treatment Units** **Model: Endo wise plus, iRoot Eco**
Product code:/	**EMDN code: Z121101**
Intended purpose: /	**This device is a cordless micro-motor used primarily for mechanical root canal preparation with integrated apex locator for endodontic treatment. While root canal preparation is made, the root canal measurement can be simultaneously carried out. Alternatively, the Independent apex locator measurement is possible, using the separate lip hook for measuring file.**
Basic UDI-DI:/	**697107537EndowiseplusYT, 697107537iRootEco35**
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