Declaration of Conformity
To Council Directive 93/42/EEC

Manufacturer: Foshan Anle Medical Apparatus Co., Ltd
2 Flat, No.7, C District, Technology, & Industry Garden, Sanshui Centre, 528137
Foshan,Guangdong.PEOPLE'S REPULIC OF CHINA

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175 fax: +49-40-255726

Product**:** Integral Dental Unit

Model: AL-388S1,AL-388S2,AL-388S3,AL-388S4,AL-388SC,AL-388SD,AL -398AA-1,AL-398AA,AL-398BB,AL-398HB,AL-398HF,AL-398HG,AL-398Sanor'e,AL-398HC

Classification: **IIa, According to MDD 93/42/EEC Annex** IX/**Rule 9**

Conformity assessment Route: MDD 93/42/EEC, Annex V.

We(Foshan Anle Medical Apparatus Co., Ltd) declare at our sole responsibility that products comply with requirements of directive 93/42/EEC of 14 June 1993 concerning medical devices; including, at 21 march 2010, the amendments by council directive 2007/47/EEC.
All Supporting documentation is retained at the premises of the manufacturer.

Notified body: **TÜV SÜD Product Service GmbH**
Ridlerstraße 65 80339 Munich Germany

Identification number: CE **0123**

(EC) Certificate(s): G2 0584820010 Rev.00
Certificate validity: 2024-05-26
Start of CE-marking: 2006-07-07
Place, date of issue: Foshan City, Guangdong, P.R.China. 2021.3.18

Signature: Name Mr. Peng Bo (General Manager)

FOSHAN ANLE MEDICAL APPARATUS CO., LTD. 佛山市安乐医疗器械有限公司