

# Declaration of Conformity

**Manufacturer:** FOSHAN ANLE MEDICAL APPARATUS CO., LTD.

**Address:** 2 Flat, No.7, C District, Technology & Industry Garden, Sanshui Centre, Foshan City, Guangdong Province, P.R.China.

**European:** Shanghai International Holding Corp. GmbH(Europe).

**Representative:** Eiffestrasse 80, D-20537 Hamburg Germany.

**Product:** INTEGRAL DENTAL UNIT

**Model Code:** AL-388SA, AL-388SB,AL-388SC, AL-388SD, AL-398Sanor'e, AL-398HF, AL-398HA, AL-398HB, AL-398HG, AL-398AA-1, AL-398AA

**Classification (MDD, Annex IX):** IIa

**Conformity Assessment Route:** MDD ANNEX V.3

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

## DIRECTIVES

### General applicable directives:

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

### Standard:

IEC601-1:1988+A1:1991+A2:1995, IEC60601-1-2:2001, ISO6875:1995, ISO9680:1993, ISO7494-1:2004, ISO7494-2:2003.

**Notified Body:** TÜV SÜD Group China-Shanghai  
No.88 Heng Tong Road, Shanghai 200070, P.R.China.

**Certificate:** G2 16 04 58482 008

**Expirate date of the Certificate:** 2021-07-06

**Date CE mark was affixed:** 2016-07-07

**Place, Date :** July 07, 2016, Foshan City, China

**Signature:** 彭波  
**Name:** Mr. Peng Bo  
**Position:** General Manager



A handwritten signature in blue ink, consisting of stylized loops and strokes.