

CE Technical File

Declaration of Conformity No.: JS-CE-HH-01

Manufacturer Sinol Dental Limited

Address No.3 Biyuan Road, 712000 Xianyang, Shaanxi, PEOPLE'S REPUBLIC OF CHINA

European Shanghai International Holding Corp.GmbH (Europe)

Representative Eiffestrasse 80, D-20537, Hamburg, Germany

Product High Speed Air Turbine Handpiece

Model Code ADS-2(4) AZS-2(4) AXS-2(4) AD-2(4) AZ-2(4) AX-2(4) ADT-4 AZT-4 ADL-4
AZL-4 ADZ-4 AZZ-4 ADB-4 ADD-2(4) ADF-4 AZF-4 AXF-4 BD-2(4) BZ-2(4)
BX-2(4) 1397-B

Classification: II a (According to Rule 9 of MDD Annex IX)

UMDNS Code: 11161

Conformity Assessment Route: MDD Annex II excluding (4)

We, Sinol Dental Limited, herewith declare that the above mentioned product meet the provisions of the following EC Council Directive. We are exclusively responsible for this DoC. All supporting documentation is retained at the premises of the manufacturer.

DIRECTIVES

General Applicable Directive:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical device (MDD 93/42/EEC).

Notified Body TÜV SÜD Product Service GmbH,

Ridlerstr.65, D-80339 Munich, Germany

Identification Number **CE** 0123

Certificate No. G1 099406 0008 Rev.01

Date CE Certificate is Expired 2024-01-22

Date CE mark was affixed 2005-11

Place, Date of Declaration Xianyang, 2019-01-23

Signature  Dou Bo

Position General Manager

Revision: 5.4 Date: Jan., 2019