Declaration of Conformity

Manufacturer:

FOSHAN AKOS MEDICAL INSTRUMENT CO., LTD

Room301,3F,Unit A,Building No.4,Zone B,HAO Science Park,Nanhai District, Foshan City,China

Whose single Authorized Representative:

SUNGO Europe B.V
Olympisch Stadion 24, 1076 DE Amsterdam, Netherlands

We, the manufacturer, herewith declare that the products

Dental high speed air turbine handpiece

Model: K9, X3, X2, K1, K6, N5, N8

Umdns code: 11161

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **IIa**, Rule 9 according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE **0123**

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC, as amended by Directive 2007/47/EC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV SÜD Product Service Gmbh

Ridlerstraße 65 • 80339 München • Germany

Certificate No.: Q6 104331 0003 Rev. 00

Issue date: 2020-03-09

Expiry date: 2023-03-08

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

We herewith declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

General Manager

Place, date：Foshan 2020-03-12

Legally binding signature, Function