
EC DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC.

Doc: CK3-E14.1 rev.: D date: 2021.9.18

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: Tealth Foshan Medical Equipment Co.,Ltd.

No.4, Qiling Road, Lutang Industrial Zone, Luocun,
Shishan Town, Nanhai District, Foshan, Guangdong
528226, China

Name and address of Authorized
Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

We declare under our sole responsibility that

the medical device: Dental Low Speed Air Turbine Handpiece, to include air motor,
contra-angle handpiece and straight handpiece

Model of low-speed air turbine handpieces: 1020L-M4, 1020-M4, 1020-B2, 1021-M4, 1024-B2, 3200CH, 3201CH,
3203CH, 3040CH
of class: Ila rule 9

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration
is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure:

Directive 93/42/EEC Annex II (excluding section 4)

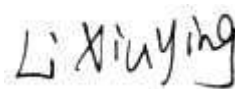
Registration No.:

CN19/41107

Notified Body:

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Li Xiuying



Foshan, Guangdong

Place, date / 2021.9.18

General Manager:

Name and function