TÜVRheinland

APPROVAL

EC Directive 93/42/EEC Annex II, Article 3 Full Quality Assurance System Medical Devices

Registration No.: HD 60039923 0001

Report No.: 15041030 001

Manufacturer: Mident Industrial Co., Ltd.

No.26 Jiaotong Road, Jinshui District

450052 Zhengzhou, Henan

China

Scope:

Design/Development and Manufacture of Air Turbine

Handpiece

Replaces Approval, Registration No.: DD 60023198 0001

Date of Expiry:

02.09.2023

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Date 01.09.2019

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

(E The CE marking may be used if all relevant and effective EC Directives are complied with.