TÜVRheinland®

APPROVAL

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

Registration No.: HD 60036447 0001

Report No.: 17018093 001

Manufacturer: Shenzhen Caremed Medical
Technology Co., Ltd.
Zone B, 3/F, 11 Building,
Hebei Industrial Area,
Longhua office, Longhua New District,
518109, Shenzhen,
China

Scope: Design and Development, Manufacture of
Ultrasonic Transducers

Date of Expiry: 26.01.2022

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 22.02.2019

Dipl.-Ing. D. Meier

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.

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