

# EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

**ChangZhou BoMedent Medical Technology Co., LTD.**  
NO.9 Changyang road, west taihu  
Science & technology Industrial Park, Changzhou  
City, jiangsu, China, 213100

**Caretechion GmbH**  
Niederrheinstr 71, 40474 Duesseldorf,  
Germany

We, the manufacturer, herewith declare that the products

Dental Electrical Motors UMDNS-Code: 11161

Apex locator UMDNS-Code: 16355

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

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

**CE 0197**

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

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

**TÜV Rheinland LGA Products GmbH**  
Tillystraße 2, 90431, Nürnberg, Germany  
Certificate No :DD 60143320 0001  
Issue date: 2019-09-30  
Expiry date:2024-05-27

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

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

The above mentioned declaration of conformity is exclusively under the responsibility of

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Changzhou, China.  
Place, date

2020. 7. 29

