EC Declaration of Conformity

Manufacturer：
Ningbo Greatcare Trading Co.,Ltd.
Unit 93,Building 12, No.818,Qiming Road,
Yinzhou, Ningbo, China

whose single Authorized Representative:
Greatcare Medical GmbH
Bonner Str. 31, 50389 Wesseling，
Germany DIMDI No.: DE/00000 44366

We, the manufacturer herewith declare that the products:

Non-rebreath Mask

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 manufacturer under a quality management system according to Annex Ⅴ 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:
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TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: **DD 60146173 0001**

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 documents for the respective batch of produced devices.

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

Company:Ningbo Greatcare Trading Co.,Ltd.
Address: Unit 93, Building 12, No.818 Qiming Road, Yinzhou, Ningbo, China

Ningbo ,China March 21,2021

Place, date

Liu ting 宁波冠克贸易有限公司 NINGBO GREATCARE TRADING CO.,LTD.

Legally binding signature, function

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