Greatcare
Creating a Better Care

Verson: 01

EC Declaration of Conformity

Manufacturer:

Ningbo Greatcare Trading Co., Ltd.
Unit 93, Building 12, No. 818, Qiming Road,
Yinzhou, 315105 Ningbo, Zhejiang China

Whose single Authorized Representative:

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

Declares that the MDR described hereafter

Disposable Medical Razor

EMDN code：V0199

Model: GCS000101/ GCS000102/ GCS010101/ GCS010103/ GCS000104/ GCS000105/ GCS000106/ GCS000121/ GCS000122/ GCS000123/ GCS000215/ GCS000201/ GCS000216

Basic UDI-DI: 697442996razorPP

SRN: CN-MF-000013676

And SRN:DE-AR-000005587 suit for EC-Rep

This Declaration of Conformity is issued under the sole responsibility of the manufacturer: Ningbo Greatcare Trading Co., Ltd

Conformity Assessment Route Annex II and Annex III according to EU 2017/745. Applicable Standard:

EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016; EN 62366-1:2015; MEDDEV 2.7/1 Rev. 4:2016; ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-05:2009.

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them, The medical device has been assigned to Class I, based on rule 1 of Annex VIII Chapter III of the Regulation EU 2017/745 MDR. It bears the mark

CE

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the “final inspection report” of the device

Ningbo， May 6. 2022 ,regulatory person

Place, date

Name ,function