



Compower®

厦门康勃医疗科技有限公司

Xiamen Compower Medical Tech. Co., Ltd.

Declaration of Conformity

Manufacturer: Xiamen Compower Medical Tech. Co., Ltd.
Unit 301, No.16, Xianghong Road, Xiang'an Torch Industrial Zone, 361101 Xiamen, PEOPLE'S
REPUBLIC OF CHINA.

European Representative: Shanghai International Holding Corp. GmbH (Europe)

Product Name: Anesthesia Mask

Object of the declaration: Article#/Product code:

0#,1#,2#,3#,4#,5#,6#,0S#,1S#,2S#,3S#,4S#,5S#,6S#,0-A#,1-A#,2-A#,3-A#,4-A#,5-A#,6-A#,0-N#,
1-N#,2-N#,3-N#,4-N#,5-N#,6-N#, 0-X#, 1-X#,2-X#,3-X#,4-X#,5-X#,6-X#,1-S#,2-S#,3-S#,4-S#,
5-S#,6-S#,0-G#, 1-G#, 2-G#, 3-G#, 4-G#, 5-G#, 6-G#, 3-Z#, 4-Z#, 5-Z#, 000-Y#, 00-Y#, 0-Y#, 1-Y#,
2-Y#

Lot No.: Pending

Number of products: Pending

UMDNS Code: 12453

Classification (MDD, Annex IX): IIa, rule 2

Conformity Assessment Route: Annex V

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TÜV SÜD Product Service GmbH,
Ridlerstr. 65, 80339, Munich, Germany

Identification number: CE0123

(EC) Certificate(s): G2 063744 0018 Rev. 02

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2020-11-04

Place, Date of Issue: XIAMEN 2020-11-17

Signature: 

Name: Frank Lin, Xiamen Compower Medical Tech. Co., Ltd.

Position: General Manager