

Declaration of Conformity

Manufacturer: **XUZHOU MAICUFF TECHNOLOGY CO.,LTD**

8#-2-1106 Jinxiujiayuan, Jianguo West Road, 221006, Xuzhou City, China

Factory Add: **3rd Floor, D Building, NO.47 Zhujiang Road, Tongshan District, Xuzhou City, China**

EC Representative: **MedNet EC-Rep GmbH**

Address: **Borkstrasse 10, 48163, Muenster, Germany**

Product Name: **Spo2 Sensor**

Model: **Disposable Spo2 Sensor**

GMDN Code: **31658**

Classification (MDD, Annex IX): **IIb, Rule 10**

Conformity Assessment Route: **Annex II excluding (4)**

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.

Manufacturer is exclusively responsible for the DOC.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC amended by DIRECTIVE 2007/47/EC of 5 September 2007

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

NB Identification number: **0123**

EC Certificate No.: **G1 093032 0005 Rev.00**

Valid from: **2020-01-20**

Valid until: **2024-05-26**

Place, Date of Issue: **XUZHOU, 2020-05-08**

Signature: 

Name: **Li Zhaoqian**

Position: **CEO**

Declaration of Conformity (DOC) Corrigendum

Product name: Spo2 Sensor

Model: Disposable Spo2 Sesnor

Class: IIb, Rule 10

Date of the DOC: 2020-05-08

This corrigendum intends to add the following information in DoC(s) of the above listed product(s).

Model:

M1401-002A, M1401-002P, M1401-002I, M1401-002N, M1501-002A, M1501-002P, M1501-002I, M1501-002N,
M1601-002N, M1601-002P, M1701-002N, M1701-002P, M1404-003A, M1404-003P, M1404-003I, M1404-003N,
M1504-003A, M1504-003P, M1504-003I, M1504-003N, M1604-003N, M1604-003P, M1704-003N, M1704-003P,
M1402-001A, M1402-001P, M1402-001I, M1402-001N, M1502-001A, M1502-001P, M1502-001I, M1502-001N,
M1602-001N, M1602-001P, M1702-001N, M1702-001P, M1409-006A, M1409-006P, M1409-006I, M1409-006N,
M1509-006A, M1509-006P, M1509-006I, M1509-006N, M1609-006N, M1609-006P, M1709-006N, M1709-006P,
M1412-008A, M1412-008P, M1412-008I, M1412-008N, M1512-008A, M1512-008P, M1512-008I, M1512-008N,
M1612-008N, M1612-008P, M1712-008N, M1712-008P, M1412-068A, M1412-068P, M1412-068I, M1412-068N,
M1512-068A, M1512-068P, M1512-068I, M1512-068N, M1612-068N, M1612-068P, M1712-068N, M1712-068P,
M1437-002A, M1437-002P, M1437-002I, M1437-002N, M1537-002A, M1537-002P, M1537-002I, M1537-002N,
M1637-002N, M1637-002P, M1737-002N, M1737-002P

According to Regulation (EU) 2017/745 (MDR), for legacy devices according to Art. 120 (3), no changes to DOCs signed prior to May 26, 2021 can be performed. In case of the above described non-significant change(s) (as defined in MDCG 2020-3), the existing DOC(s) is (are) still valid and this Corrigendum will be attached to the originally signed DOC(s). The DOC(s) will be updated upon transition to MDR.

Xuzhou, 2022-11-16

Place/Date



legally binding signature

Li Zhaoqian / CEO

Name and function



徐州迈康科技有限公司

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Declaration of Conformity (DOC) Corrigendum- No.2

Product name: Spo2 Sensor

Type: Disposable Spo2 Sensor

Class: IIb, Rule 10

Date of the DOC: 2020-05-08

Date of the 1st Corrigendum: 2022-11-16

This corrigendum intends to add the following information in DoC(s) of the above listed product(s).

Correct old Manufacturer: XUZHOU MAICUFF TECHNOLOGY CO.,LTD

8#-2-1106 Jinxiujiayuan, Jianguo West Road, 221006, Xuzhou City, China

To new Manufacturer: Xuzhou Maicuff Technology Co.,Ltd.

8#-2-1106 Jinxiujiayuan, Jianguo West Road, 221006 Xuzhou City, Jiangsu Province

PEOPLE'S REPUBLIC OF CHINA

Correct old Factory Add: 3rd Floor, D Building, NO.47 Zhujiang Road, Tongshan District, Xuzhou City, China

To new Factory Add: No.21 Jingwei Road, Xuzhou High-Tech Industrial Development Zone 221116 Xuzhou City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

According to Regulation (EU) 2017/745 (MDR), for legacy devices according to Art. 120 (3), no changes to DOCs signed prior to May 26, 2021 can be performed. In case of the above described non-significant change(s) (as defined in MDCG 2020-3), the existing DOC(s) is (are) still valid and this Corrigendum will be attached to the originally signed DOC(s). The DOC(s) will be updated upon transition to MDR.

Xuzhou, 2023-09-06

Place/Date

legally binding signature

Li Zhaoqian / CEO

Name and function