

DECLARATION OF CONFORMITY

We

Name and address of manufacturer: Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone
Menggang, Changyuan county 453400 Henan
People's republic of china

declare on our own responsibility that

the medical device: Surgical Mask
type or model: Ear loop
Tie band

meets all applicable requirements of the Directive 93/42/EEC Annex I, as amended by Directive 2007/47/EC

Applied standards : *The list of applied standards, See attachment 1*

Classification: Classified as class I non sterile according to Annex IX, rule 1 of the Directive 93/42/EEC.

Conformity assessment procedure: *Conformity assessment was performed according to Annex VII of the Directive 93/42/EEC.*

The Authorized Representative within the EU who has been empowered to enter into commitments on our behalf is: *MedNet EC-REP GmbH
Barkstrasse 10
48163 Münster, Germany*

2024-5-26
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Validity period

2020-03-03
.....

place, date

Name: Mr.Yuxian Zong
Function: Management Representative
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Attachment 1 Standards Applied

Standards Applied

EN ISO 15223-1: 2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)

EN 1041: 2008+A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 10993-1:2009/AC:2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Technical Corrigendum 1 (ISO 10993-1:2009/Cor 1:2010)

EN ISO 10993-5: 2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity (ISO 10993-5: 2009)

EN ISO 10993-10: 2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)

EN ISO 13485:2016 Medical devices -Quality management systems -Requirements for regulatory purposes (ISO 13485:2016)

EN ISO14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

EN 14683:2019 Medical face masks – Requirements and test methods