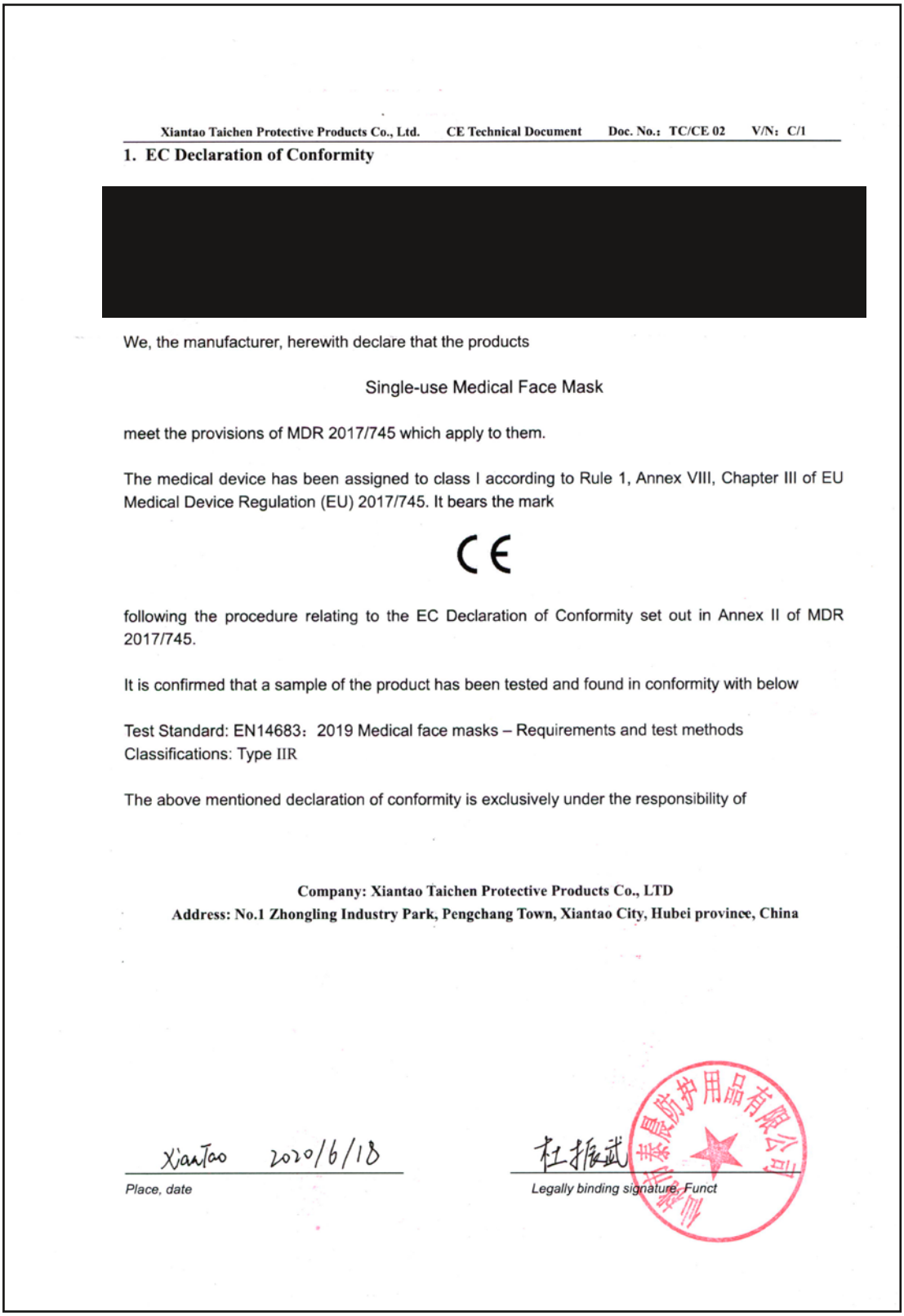
Zertifikate
MNS_T2R_8 | Mund-Nasenschutz



Xiantao Taichen Protective Products Co., Ltd. CE Technical Document Doc. No.: TC/CE 02 V/N: C/1

1. EC Declaration of Conformity

[redacted]

We, the manufacturer, herewith declare that the products

Single-use Medical Face Mask

meet the provisions of MDR 2017/745 which apply to them.

The medical device has been assigned to class I according to Rule 1, Annex VIII, Chapter III of EU Medical Device Regulation (EU) 2017/745. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex II of MDR 2017/745.

It is confirmed that a sample of the product has been tested and found in conformity with below

Test Standard: EN14683：2019 Medical face masks – Requirements and test methods
Classifications: Type IIR

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

Company: Xiantao Taichen Protective Products Co., LTD
Address: No.1 Zhongling Industry Park, Pengchang Town, Xiantao City, Hubei province, China

Xiantao 2020/6/18
Place, date

杜振武
Legally binding signature, Funct

Käufer erhalten das ungeschwärzte Zertifikat

中国认可
国际互认
检测
TESTING
CNAS L0599

[redacted]

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	Disposable protective face mask
SGS Internal Ref No.	:	WHIN2005001155SC
Style No.	:	TC0604
Sample Color	:	Blue
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	May 27, 2020
Testing Period	:	May 28, 2020 - Jun 17, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Käufer erhalten das ungeschwärzte Zertifikat

Test Result

Medical Face Masks-Requirements and Test Methods
(EN 14683:2019+AC:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)
(EN 14683:2019 Annex B)

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.9	99.9	99.9	99.9

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%

Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm^2)	52	49	51	53	51

Remark: Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Fail	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Fail	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			30				
Overall result:			Acceptable				

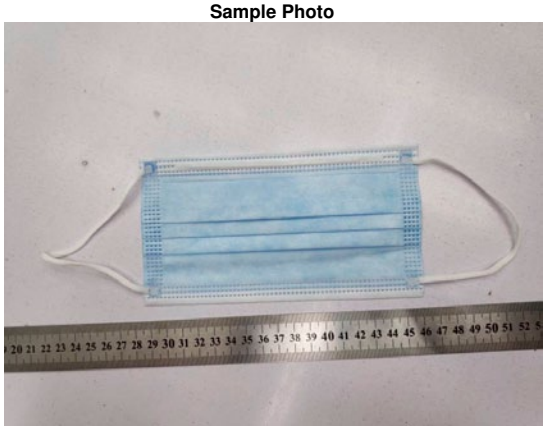
Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

	1#	2#	3#	4#	5#
CFU/g	3	4	3	6	4

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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