DECLARATION OF CONFORMITY

MANUFACTURER	**Hunan Bei Er An Qin Medical Technology Co., Ltd.** No.502 Juxing Chuangye Jidi, No. 8, Lujing Road, Changsha High-tech Development Zone, Changsha City, Hunan Province, P.R.China
EUROPEAN REPRESENTATIVE	CMC Medical Devices &Drugs S. L. C/ Horacio Lengo n18 · C. P 29006 · Málaga-Spain
PRODUCTS	Medical Face Mask
MODEL CLASS	Class I
CONFORMITY ASSESSMENT	MDD 93/42/EEC Annex IX

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

STANDARDS APPLIED	EN ISO 15223-1:2016	EN ISO 14971:2012
	EN ISO 14683:2019	EN ISO 1041:2008
	EN ISO 10993-5:2009	ISO 10993-10:2010

PLACE Changsha/ China

DATE OF ISSUE 2020-04-27

SIGNATURE

Hunan Bei Er An Qin Medical Technology Co.,Ltd.
General Manager
4301990024

CE

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/12052020.20

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized

Hunan Bei Er An Qin Medical Technology Co.,Ltd
No.502 Juxing Chuangye Jidi, No.8, Lujing Road, Changsha High-tech Development Zone, Changsha City, Hunan Province, P.R.China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/782/2020**

CE

Issued on: 12/05/2020

Valid until: 11/05/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Medical face mask

CE

Test Report SL52025257806001TX Date:June 09,2020 Page 1 of 3

HUNAN BEI ER AN QIN MEDICAL TECHNOLOGY CO.,LTD.
NO.502 JUXING CHUANGYE JIDI,NO.8 LUJING ROAD,CHANGSHA HIGH-TECH DEVELOPMENT ZONE,CHANGSHA CITY,HUNAN PROVINCE

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

Sample Description	:	Medical face mask (Non-sterile)(Type II)
Style No.	:	PM-G-D
Composition	:	melt-blown fabric/ non-woven fabric
Sample Color	:	blue
Manufacturer	:	HUNAN BEI ER AN QIN MEDICAL TECHNOLOGY CO.,LTD.
Proposed Care Instruction	:	/
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	May 15, 2020
Testing Period	:	May 18, 2020 - Jun 09, 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).

Comment:

Medical Face Masks-Requirements and Test Methods(EN 14683:2019+AC:2019)	
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.5 Microbial Cleanliness	M

Remark: M=Meet EN 14683:2019+AC:2019 Type II requirement
F=Below EN 14683:2019+AC:2019 Type II requirement

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

Sara Guo (Account Executive)

Dongjing Liu (Authorized Signatory)

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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), %	99.8	>99.9	99.8	99.7	99.7

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

* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CMA (China Metrology Accreditation).

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

	1#	2#	3#	4#	5#
Differential pressure △ P (Pa/cm^2)	39	39	32	34	36

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

Clause 5.2.5 Microbial Cleanliness
(EN ISO 11737-1:2018)

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

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

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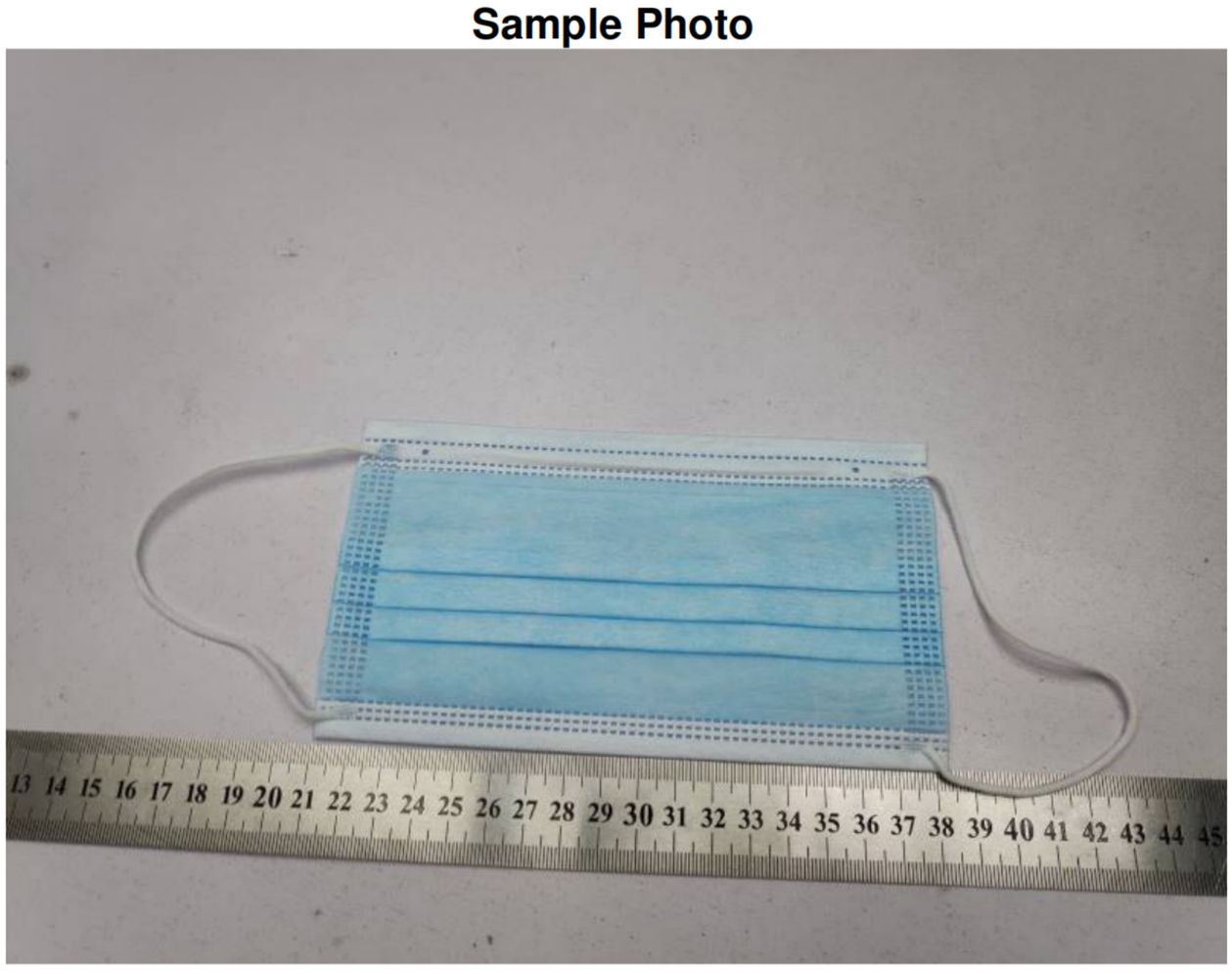
Sample Photo



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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