DANAK
PROD Reg. nr. 7020

FORCE Certification

EU Type-Examination Certificate

Regulation on Personal Protective Equipment (Module B)
Temporary approval of filtering half mask to protect against COVID-19
Certificate No.: 0200-PPE-08751 version 1

FORCE Certification A/S (EU-notified body number 0200) has in accordance with the provisions of Recommendation for use No. PPE-R/02.075 and the basic principles of Regulation (EU) 2016/425 of The European Parliament and of The Council of 9 March 2016, issued a temporary EU type-examination certificate to:

Manufacturer:	**Yancheng Xiangbang Medical Equipment Co., Ltd.**

For manufacturing the following personal protective equipment:

Type/Description:	**Filtering half mask to protect against COVID-19**
Model/Designation:	**XB0116**
Test scheme:	**Recommendation for use PPE-R/02.075 version 2**
Category:	**III**
Restrictions for use:	**Temporary and limited approval of filtering half mask to protect against COVID-19. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.**

The examined sample of personal protective equipment is found to fulfill the relevant requirements of the applied test scheme(s) and to be in compliance with the applicable essential health and safety requirements of Regulation (EU) 2016/425. Documentation for observance of relevant requirements and the basis for the type examination are described in the appendix to this certificate. The manufacturer shall inform FORCE Certification A/S of any contemplated changes.

The validity of this conformity assessement certificate is less than one year. Annual production control according to Regulation (EU) 2016/425 module C2 or D have not been assessed. The certificate may be prolonged following a re-examination of the product(s).

Date of issue [yyyy-mm-dd]: **2020-07-09**
Date of expiry [yyyy-mm-dd]: **2021-01-09**

Søren Bo Jensen
Certification Manager

Erik Bjarnov
Examiner

CE

FORCE Certification A/S task No.: **120-27744** / Certificate ID: **08751**

This certificate will remain valid unless cancelled, revoked or expired, provided the conditions in the attached appendix are complied with, and that the equipment remains state of the art within its applicable field of service. Status of this certificate can be verified on www.forcecertification.com. This EU Type-Examination Certificate is the property of FORCE Certification A/S. Extracts of this certificate may only be reproduced with a written permission from FORCE Certification A/S.

Appendix to EU type-examination certificate

Temporary and limited approval of filtering half mask to protect against COVID-19

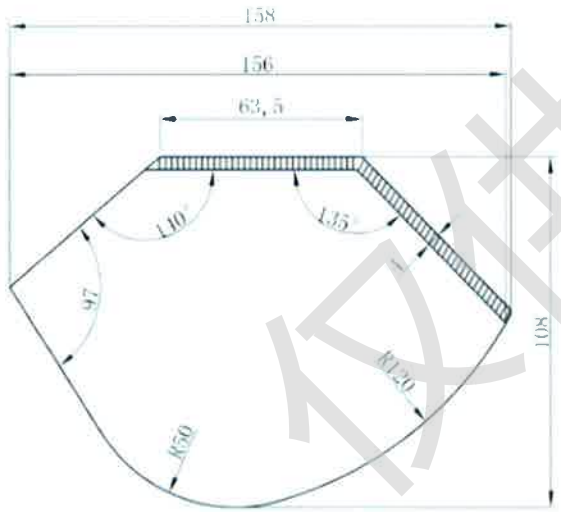
Certificate No.: 0200-PPE-08751 version 1
Issued by FORCE Certification A/S - EU-notified body number 0200

Manufacturer:	Yancheng Xiangbang Medical Equipment Co., Ltd. No.5 Minjiang Road, Yancheng City Jiangsu Province China

Identification of personal protective equipment:

Type/Description:	Filtering half mask to protect against COVID-19
Model/Designation:	XB0116
Test scheme:	Recommendation for use PPE-R/02.075 version 2
Restrictions for use:	Temporary and limited approval of filtering half mask to protect against COVID-19. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.
Category:	III

Design:



XB0116

Appendix to EU type-examination certificate

Temporary and limited approval of
filtering half mask to protect against COVID-19

Certificate No.: 0200-PPE-08751 version 1
Issued by FORCE Certification A/S - EU-notified body number 0200

History:

Issue/change:	Certificate No.:	Certificate ID:	Issue date:
- Original certificate	0200-PPE-08751 version 1	08751	2020-07-09

Place(s) of Production:

Final assembly	Address
Yancheng Xiangbang Medical Equipment Co., Ltd.	No.5 Minjiang Road, Yancheng City Jiangsu Province China

Appendix to EU type-examination certificate

Temporary and limited approval of
filtering half mask to protect against COVID-19

Certificate No.: 0200-PPE-08751 version 1
Issued by FORCE Certification A/S - EU-notified body number 0200

Documentation for observance of relevant technical requirements stated in the applied test scheme:

Test house	Report No.:	Testing/Inspection of:
- FORCE Technology	120-27744	RfU 02/075 type-examination of filtering half mask

Partial conclusion: The requirements stated in the applied test scheme are fulfilled for the relevant test clauses and nominal protection factor.

Further documentation for observance of relevant/limited requirements stated in Annex III of Regulation (EU) 2016/425:

- Risk assessment:	OK, included in the application signed 2020-06-23
- List of applicable EHSR	OK, included in the application signed 2020-06-23
- List of materials and sub-suppliers	OK, received documentation for "Drawing&Assembly"
	OK, received documentation for "Materials&components&suppliers"
- Description of quality system	OK, received documentation for "Quality control-raw material"
	OK, received documentation for "Standardized work instruction"
- User information and marking	OK, markings on packaging
	OK, markings on mask
	OK, user instruction
- Declaration of innocuousness	OK, included in the application signed 2020-06-23

The user information and marking were assessed in English.

Conclusion

Based on the above-mentioned attestation it can be concluded that the filtering half mask to protect against COVID-19, designated XB0116, meets the conditions of a temporary and limited approval according to Regulation (EU) 2016/425.

FORCE Certification A/S task No.: 120-27744
Date: 2020-07-09

Erik Bjarnov
Examiner

Yancheng Xiangbang Medical Equipment Co., Ltd
No 5, Minjiang Rd, Yancheng City, Jiangsu, China
224000 Yancheng
China
Att. Gordon Guo

Brøndby, 23 June 2020
120-27744

rafb/szp

Test Report

Yancheng Xiangbang Medical Equipment Co., Ltd,

FORCE Technology Norway AS,
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NO-1395 Hvalstad, Norway
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Fax +45 43 25 00 10
force@force.dk
www.forcetechnology.com

Test report

Object: Test of mask marked "KN95"

Samples received: 02.06.2020

Sampling by: Yancheng Xiangbang Medical Equipment Co. Ltd

Method: RFU 02.075 version 2

Test date: 16.06.2020-19.06.2020

Results:

§ 8.2 Visual inspection

The mask was of uniform white material and without valve. The mask had white straps that fit around the ears.

§ 8.4 Practical performance

	Comments
a) Head harness comfort	Ok
b) Security of fastenings	Ok
c) Field of vision	Ok
d) Maintenance of face seal	Ok
e) Other comments	Ok

Table 1: Practical performance

§ 8.7 Carbon dioxide content of the inhalation air

Three test fits of the mask were measured. The average was 0,57%. The requirement in EN 149 is <1,0%.

§ 8.9 Breathing Resistance

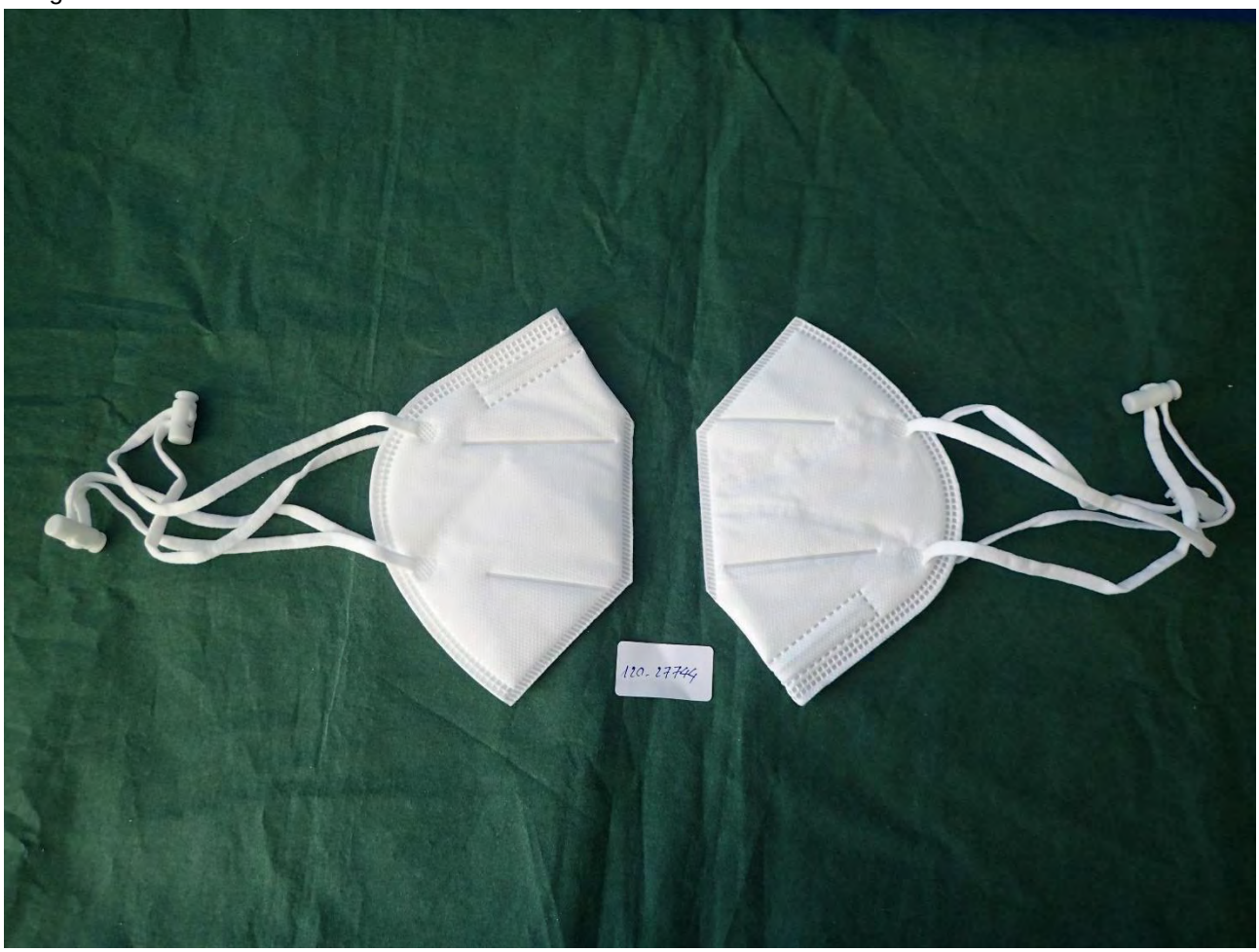
The requirements of EN 149:2001 + A1:2009 is listed in the table below.

Sample	Result (mbar)	Requirements (mbar)	Parameter
"KN95" mask	0,53	<0,7	(Inhalation, 30 l/min)
	1,80	<2,4	(Inhalation, 95 l/min)
	2,85	<3,0	(Exhalation, 160 l/min)

Table 2: Breathing resistance

Image 1:

Image 2:



TÜVRheinland®
Precisely Right.

Test Report No.: 178140670a 001

Client: **Yancheng Xiangbang Medical Equipment Co., Ltd**
No 5, Minjiang Rd, Yancheng City, Jiangsu, China

Contact Person: Gardon Guo

Sample Description As Declared :

No. Of Sample	:	90 Pcs
Product Description	:	KN95 Face Mask
Model No.	:	XB0116
Sales Destination(country)	:	Europe(country name not provided)
Test type	:	Partial test
Product type	:	Single shift use only
Claimed Classification	:	FFP2 NR

Sample obtaining method: Sending by customer

Sample Receiving date: 2020-05-26
Delivery condition: *Apparent good, Samples tested as received*
Test Period: 2020-05-28 to 2020-07-13

Test specification:	***Test result:***
Particulate respirator-half facepiece EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking^	Please refer to result page

For and on behalf of

TÜV Rheinland / CCIC (Qingdao) Co., Ltd.

2020-07-14 Alex Zhou / General Manager

Date *Name/Position*

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Material list

Material	Color	Location
Textile	White	White folding mask

Note:

	Shading shows the clauses requested
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "result details section for more information.
Fail	Requirement not satisfied. Refer to the "result details section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

Result:

EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirement, testing, marking.

7.4 **Package^** **PASS [1]**

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.
Note 1: In accordance with the requirement.

7.5 **Material^** **PASS [2]**

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.
Note 2: In accordance with the requirement.
Specimens -14, -15, -16 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.
Specimens -01, -02, -03 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

7.6 **Cleaning and disinfecting^** **NAp [3]**

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.
Note 3: Single shift use only.