CELAB®
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CERTIFICATE

Certificate Number **UCN**	: **802713544823**
Job	: J29091
Date of Issue	: *2020-03-15*
Certificate valid up to	: *2024-03-14*
Brand Name	: *See Label*
Type	: *YIFAN COMFORTABLE THREE-LAYERS NURSING MASK*
Model N	: *K03*

Standard Used : EN 14683:2005

Conclusion :
After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✔ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : ESC-SZYH-202003-MDD-1	✔ OK
Presence of CE symbol in the product label.	✔ OK
Presence of instruction manual	✔ OK
Use of valid Harmonized standard in the declaration of conformity	✔ OK
Presence of product description in the technical construction file	✔ OK

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
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Annex : Regulation for Voluntary Certification Activities

1. Release of certificate

These certificates are issued on a voluntary basis on request of manufacturer.
The certificate is released for product after inspection of the documentation relative to the technical construction file.
This Certificate is released only after that, is opinion of a CELAB approved technician, that the technical construction file (test reports, documentations, instruction manuals) demonstrate that the essential requirements indicated in the directives himself was covered.
Note: the technical requirement are related to the physical propriety of a product and his production process and not the legal requirements of directives.
When the opinion is positive, the certificate is released.
The inspection provided by CELAB is not relative to: The product; The production; The law requirements; The work performed or that will be performed by Notified Bodies.
The Inspection cover ONLY the following aspects (where applicable):

- Presence of declaration of conformity;
- Presence of test report as indicated in the certificate ;
- Presence of CE symbol in the product label template;
- Presence of Instruction manual;
- Use of actual harmonized standards as for EU official Journal;
- Presence of production description in the technical construction file.

2. Validity of certificate

All certificate have 4 years of validity. After such time the certificate will not be any more valid.

3. Withdraw of certificate

The certificate are withdraw if there is a reasonable justification that the product do not comply with the requirement of a directive, or when this agreement was not addressed.

4. Responsibility of manufacturer

As many directives require use of a Notified Body, in such case is responsibility of producer or his representative in Europe to follow all applicable directives requirement and contact.
This regulation will always be consigned together with the certificate and is a part of them, use of the certificate without text of this regulation is not allowed or accepted.
Is responsibility to the manufacturer to comply with CE marking law prescriptions.

5. Responsibility of CELAB

CELAB take no responsibility on product tested except that, in case of advice from market, CELAB will investigate on such compliant and, if found acceptable, the certificate will be withdraw.
CELAB is not responsible for the product, the production, the importing, the distribution, the sales, the advertisement, the technical assistance, the consulting or as EU mandatories.
Certificate is the result of technical opinion, given as a private owned company. There is no any warranty that the product will comply with all requirements of directives or a law.
CELAB is not responsible for CE marking of the product indicated in the certificate.

6. Responsibility of user of certificate

Is responsibility of the user of the certificate to comply with all laws requirements. Only as a general reference, the user of certificate will need to get copy of test-report from his supplier and be responsible for technical construction file. User of the certificate take full legal responsibility on such use.
Such certificate are not legal requirements except when used between private company as a specific contract agreement between them.
User of certificate need to full comply with applicable requirements indicated in such directives. User of certificate are not allowed to induce the market on a different destination of use of the certificate different from what stated in this agreement. Use of certificate of conformity is restricted to expert in CE Marking field that can fully understand scope of this certificate and is not for general public.
This certificate cannot be publicized in a misuses or in a way that It can confuse general public. The user of the certificate will Always do not use the certificate for customs control or public authority requirement control.

7. Scope of the certificate.

The ONLY Scope of this kind of certificate is :

- Allow the manufacturer to demonstrate to a customer that a product was tested without need to give him test reports (if both accepted by manufacturer and by the customer);
- Allow a private customer to have an evidence that an independent 3th part have inspected the documentation on voluntary basis.

The certificate provide an added value for manufacturer in situation where the manufacturer don't want to provide to his customer the test reports (if not required by law).
Such certificate will need to be used only as demonstration that a sample of a product was really tested between companies that recognize this agreement. Such certificate are not required by law (as they are voluntary certificate), and are intended to be used between private company for commercial issue. These certificate where not to be used to demonstrate conformity of the product to authority or for government control. The certificate are not an authorization by CELAB to put the CE marking on the product.
The Certificate is not a legal requirement for CE marking activities. Is the opinion of CELAB that manufacture can provide the CE marking in the product IF he comply with all prescription of the directives. The Certificate is not a declaration of conformity or an attestation of conformity. Note that some directive require use of Notified Body, the certificate of conformity and the certificate of compliance are NOT related to Notified Body work and are not related to law requirements.
The certificate is a Technical Opinion issued by CELAB to the manufacturer of the product where, after review of document issued by manufacturer, CELAB certify his opinion regarding the conformity between the product and the prescription of the standard and/or the technical requirement of the directive.
The certificate where not issued in the role or the task of Notified Body or accredited testing laboratory or accredited certification body. Warning : do not confuse this certificate with certificates issued by notified bodies. In case of doubt on using this certificate, do not use it and consult a consultant or expert or contact CELAB for request of information at celab@celab.com

8. Technical construction File storage

The technical construction file is normally not stored in CELAB archives, after review of CELAB the documents were not archived in the CELAB databases. Is responsibility of the manufacturer that the documents is available for law requirements. CELAB is not responsible for the storage of the technical construction file.
Note : that the technical construction files for activities related to CE marking will need to be available in Europe.

9. CE Marking General information's

All person/company/body involved on a CE marking product are responsible to perform all task indicate in the directive. Full text of directive can be found in European Union Web Site : http://ec.europa.eu/growth/index_en
We recommend to search in such web site full information about CE marking related directives.

CE REPORT

Prepared For:	
Manufacturer:	
Product Name:	YIFAN COMFORTABLE THREE-LAYERS NURSING MASK
Trademark:	/
Main Model:	K03
Additional Models:	/
Test Date:	Mar.02,2020 To Mar.15,2020
Date of Report :	Mar.15,2020
Report No.:	ESC-SZYH-202003-MDD-1

Massimiliano Bertoldi
General Manager – CELAB

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TEST REPORT

EN 14683:2005

Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Testing Laboratory Name	TST Testing Technology(Dongguan) Co., Ltd.
Address	2F Yinhe Building Hetian Road,Houjie Town, Dongguan, Guangdong, China
Testing location	TST Testing Technology(Dongguan) Co., Ltd.

Test specification	
Standard.....	EN 14683:2005
Test item description	YIFAN COMFORTABLE THREE-LAYERS NURSING MASK
Model and/or type reference	K03
Additional Model :	/
Rating(s).....	/

Test case verdicts		
Test case does not apply to the test object ..... :		N/A
Test item does meet the requirement ..... :		P(ass)
Test item does not meet the requirement ..... :		F(ail)

EN 14683:2014
Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Clause	Testing Items	Result
4	Classification Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant.	P
5	Requirements	P
5.1	General	
5.1.1	Materials and construction The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness (absence of particulate matter).	P
5.1.2	Design The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	P
5.2	Performance requirements	P
5.2.1	General All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.	P
5.2.2	Bacterial filtration efficiency (BFE) When tested in accordance with Annex B, the bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	P
5.2.3	Breathability When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	P
5.2.4	Splash resistance When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.	P

Clause	Testing Items	Result
5.2.5	Microbial cleanliness (Bioburden) When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested (seeTable 1). NOTE EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package. To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below: The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %. Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µ filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts. In the report, indicate the total bioburden per mask and based on the mask weigh, the total bioburden per gram tested.	P
5.26	Biocompatibility According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request. As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered.	P

<table>
<tr><td></td><td></td><td></td></tr>
<tr><td>5.2.7</td><td>Summary of performance requirements
Table 1 — Performance requirements for medical face masks
<table>
<tr><th>Test</th><th>Type I[a]</th><th>Type II</th><th>Type IIR</th></tr>
<tr><td>Bacterial filtration efficiency (BFE), (%)</td><td>≥ 95</td><td>≥ 98</td><td>≥ 98</td></tr>
<tr><td>Differential pressure (Pa/cm²)</td><td>< 29,4</td><td>< 29,4</td><td>< 49,0</td></tr>
<tr><td>Splash resistance pressure (kPa)</td><td>Not required</td><td>Not required</td><td>≥ 16,0</td></tr>
<tr><td>Microbial cleanliness (cfu/g)</td><td>≤ 30</td><td>≤ 30</td><td>≤ 30</td></tr>
<tr><td colspan="4">[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.</td></tr>
</table></td><td>P</td></tr>
<tr><td>6</td><td>Labelling and information to be supplied
Annex I, §13, of the Medical Devices Directive (93/42/EEC) specifies the information that has to be specified on the packaging in which the medical face mask is supplied.
The following information shall be supplied in addition:
a)number of this European Standard;
b)type of mask (as indicated in Table 1).</td><td>P</td></tr>
</table>

ANNEX A:

Photo-documentation