Application Form
for
CERTIFICATE OF CONFORMITY

This is a request to CELAB srl – Italy, to review the documentation related to the product indicated and to issue a voluntary certificate that will be used according to the annex regulation.

Job **: J29545**

Applicant : HEFEI C&P NONWOVEN PRODUCTS CO.,LTD
No.22 Park road,Feidong new city development area , Hefei,Anhui, China
Email : cpnonwoven@foxmail.com

Manufacturer : HEFEI C&P NONWOVEN PRODUCTS CO.,LTD
Address : No.22 Park road,Feidong new city development area,
Hefei,Anhui, China

DESCRIPTION OF THE APPARATUS

Type : Surgical mask
Brand name : C&P
Identification : 0201, 0202
Intended use : Medical Equipment

Aspect to be assessed

Standard used :
EN 14683:2005,EN ISO 14971:2012,EN ISO 15223-1:2016,EN 1041:2008,EN ISO 10993-1:2009/AC:2010

Directive used :
93/42/EEC Medical devices (MDD)

The customer declare to understand the Annex Regulation.

Customer Signature

Date : _____

Name : _____

Signature : _____

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.