# Market Surveillance:
# Standards, test reports, declarations of conformity and certificates

## A Belgian case study : FFP2

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# Overview

- Market Surveillance
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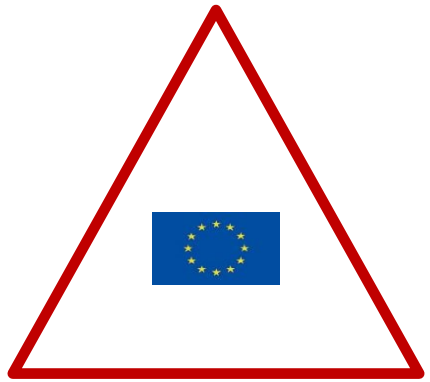
  - European legal Framework
- Conformity Assessment
  - Obligations
  - Use of Standards
  - Test Reports
  - Accreditation
  - Notified bodies
  - Declaration of Conformity
  - Certificates
  - Flow

# Goal of Market Surveillance

**Safe products**



**Level Playing Field** **Free Circulation of goods**

# European legal framework

General Safety Requirement:

Producers shall be obliged to place only safe products on the market.

Harmonised sectors :

- The directive/regulation establishes only the essential requirements the products must comply with.
- Products which do comply these requirements must be allowed by the various Member States on their respective markets.
- Products which do not meet these requirements may not be placed on the market.

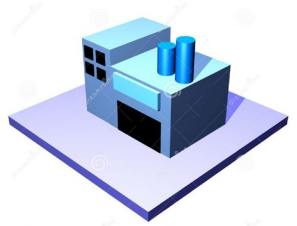
# Conformity Assessment Obligations

## Obligations of manufacturers

1. ensure that the product has been designed and manufactured in accordance with the safety objectives

2. **(harmonised sector)** draw up the technical documentation and carry out the conformity assessment procedure or have it carried out.
   - draw up an EU declaration of conformity and affix the CE marking.

   - +> Conformity assessment bodies (accredited)



# Conformity Assessment
# Use of standards

- Products manufactured in conformity with harmonised standards are presumed to be conformant to the essential requirements

- Standards are not mandatory, they remain voluntary *(Alternate paths are possible but the economic operator has an obligation to prove his products are conformant to the essential requirements)*

- Standards must offer a guarantee of quality with regard to the essential requirements of the directives/regulations

# Conformity Assessment
# Test Reports

**Testing laboratories (ISO-IEC 17025)**

- Competent
- Impartial
- Consistent

Issue Test Reports

- Testing method
- Testing results
- Fail /Pass for specific requirements

# Conformity Assessment Accreditation

## Mutual recognition *art 5*

The competent authorities of Member States of destination shall not refuse test reports or certificates that were issued by a conformity assessment body accredited for the appropriate field of conformity assessment activity in accordance with Regulation (EC) No 765/2008 on grounds related to the competence of that body.

## 765/2008 art 11.2

National authorities shall recognise the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer evaluation

# Conformity Assessment
# Notified Bodies


- A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market.
- These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required.
- The European Commission publishes a list of such notified bodies (NANDO).

# Conformity Assessment
# Declaration of Conformity

- DoC states that the fulfilment of the safety objectives has been **demonstrated**.
  - It shall be
    - continuously updated.
    - translated into the language or languages required by the Member State in which the electrical equipment is placed or made available on the market
    - signed
- The manufacturer (or authorised representative) assumes the responsibility for compliance

# Conformity Assessment Declaration of Conformity

## EU DECLARATION OF CONFORMITY

| | |
|---|---|
| Personal protective equipment: | Filtering half masks to protect against particles |
| Name and address of the manufacturer: | Changzhou Shuangma Medical Devices Co., Ltd.<br>San He Kou Development Zone, Zhenglu, Tianning Changzhou, Jiangsu, China. 213115 |
| EC Authorized Representative: | CMC Medical Devices & Drugs S.L<br>C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain<br>The manufacturer is solely responsible for issuing this declaration of conformity. |

**The manufacturer is solely responsible for issuing this declaration of conformity.**

| | |
|---|---|
| Product Name: | Filtering Half Mask |
| Product photograph: |  |
| Type/Class: | FFP2 NR |
| Model: | SMK-02 SZMDK (logo) |
| It is certified that the manufacturer's technical file and PPE have been assessed and found to meet the applicable: | Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment |
| References to the relevant harmonized standards used: | EN 149:2001+A1:2009 (Respiratory protective devices – filtering half masks to protect against particles) device classification: FFP2 NR |
| Notified body: | SGS FIMKO OY, Notifed Body 0598, Takomotie 8, FI-00380, Helsinki, Finland |
| has carried out an EU-type examination (module B) on: | 06 / 10 / 2020 |
| and issued an EU-type examination certificate | FI20/966779 |
| Notified body also carried out an EU type examination (module D) for manufacturer and issued certificate: and is valid: | CN21/42503<br>07.07.2021 – 6.7.2024 |
| Personal protective equipment shall be subject to a conformity assessment procedure as detailed in: | Article 19 (c) of the Regulation. Appropriate checks are implemented and maintained while the model is in production. |
| Under the supervision of the notified body: | SGS FIMKO OY, Notifed Body 0598, Takomotie 8, FI-00380, Helsinki, Finland |

Changzhou, 2021-12-07
changzhou, 2021-12-07
Place, date

Xu Aiping, General Manager
Xu Aiping, General Manager
Name and function


# Conformity Assessment
## Certificates

- No legal value
- Cannot be used as conclusion of conformity assessment

**CELAB®**
*Via Maira snc*
*04100 Latina*
*Italy*
celab@celab.com

# CERTIFICATE

| | |
|---|---|
| Certificate Number **UCN** | : **802118241927** |
| Job | : J24364 |
| Date of Issue | : *2018-07-24* |
| Certificate valid up to | : *2022-07-23* |
| Brand Name | : *Chnano* |
| Type | : *ZN Mask* |
| Model N | : *ZN6218, ZN6005, ZN8005, ZN8848, ZN2006* |

Manufacturer : China Nano Techonlogy Co.,Ltd.
Address : 4Floor, Hatching Building, Emigration Eco Industrial Park Management Committee, Fengjie, Chongqing, China

Standard Used : EN 149:2001+A1:2009

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:*
(EU)2016/425 Personal protective equipment (PPE)

*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<br>Test report reference : B-S180718239 | ✔ 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*
*General Manager – CELAB*
www.celab.com





Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

# Certificate of Compliance

No. BST2003147518O1SC

Certificate's Holder: ZHEJIANG JINGHU MEDICAL & HEALTH PRODUCTS CO.,LTD
NO.1-2, NO. 6, WANYANG INDUSTRIAL ZONE,BIHU TOWN,LIANDU,LISHUI,CHINA

Certification Mark: BST Testing

Product: Mask

Model(s): JH175-001

Verification to: Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

**Remark:** The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of BST , in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the BST regulation about its release and its use. The regulation can be found at www.bst-test.com. This Certificate of Compliance can be checked for validity at www.bst-test.com.
This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:
We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE *Marking Certification Procedure* through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 27 March 2020

Chief Manager
Dova

BST

Expiry date 09 March 2025

Deputy Manager
Danrtsey

**BST Testing Serevice International Co., Limited**
Flat/RM 1802B 18/F Fortress Tower 250 Klng`s Road North Point HK
Certificate Search: http://www.bst-test.com, Tel:00852-60685910, E-mail:tecc.best@gmail.com

ZUOCE CERTIFICATION AND TESTING CENTER

Providing Professional Service for Safety and Health

# CERTIFICATE OF CONFORMITY

| | | |
|---|---|---|
| Certificate No. | : | ZUOCE200328272 |
| Company Name | : | Tianjin Shenghe Aizhong Medical Technology Co., Ltd |
| Company Address | : | Tianjin free trade pilot area (central business district) Xinhua Road 3699 treasure yuan building 16 floor Tianjin Y0-16007 |
| Manufacturer | : | Tianjin Shenghe Aizhong Medical Technology Co., Ltd |
| Address | : | C3, Tianda Science Park, No. 80, 4th Street, Tianjin Economic and Technological Development Zone, China |
| Product Name and Brand | : | Civil Sanitary Mask |
| Model/specifications | : | Large size(L), Small size(S), T/CNTAC 55-2020, T/CNTAC 09104-2020 |
| Related Directives and Annex | : | Personal Protective Equipment Regulation(EU) 2016/425 and Annex III,Annex IV |
| Related Standards | : | EN 149:2001+A1:2009 |
| *Examination Intent* | : | *Examination the completeness of the Technical Documentation according to the requirements of the Personal Protective Equipment Regulation(EU) 2016/425 Annex III* |
| *Review result* | : | *During the examination of the provided Technical Documentation (No.:SHAZ-TCF-001, Revision: A/0, dated 2020-Mar-27), no Non-compliance according to the requirements of the Personal Protective Equipment Regulation(EU) 2016/425 Annex III was detected.* |
| Valid From | : | 03.28.2020 |
| Valid Until | : | 03.27.2025 |
| Authorized Signer | : | Wallace Xu |
| Job Title | : | Certification Manager |
| Date of Issue | : | 2020-03-28 |

CE

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*The CE Mark may only be used if all relevant and effective EC Directives are complied with*

ZUOCE CERTIFICATION & TESTING CENTER *Email for certificate query:certificate@zuoce.org*

*Room 809,Bulding 5, No.256 Lin Xia Road, Shanghai, China*

Certificate of Conformity

VÚBP NB 1024

# CERTIFICATE

certifikát

| | | |
|---|---|---|
| Certificate Number | : | V971262F35E |
| APPLICANT | : | Dalian Hailong Orthopedic Equipment Co., Ltd Xinghai International Financial Center, Shahekou District, Dalian City, Liaoning Province, China |
| MANUFATURER | : | Dalian Hailong Orthopedic Equipment Co., Ltd Xinghai International Financial Center, Shahekou District, Dalian City, Liaoning Province, China |
| PRODUCT | : | Non-sterile Disposable Medical Mask/Non-sterile Medical Protective Mask/Sterile Disposable Medical Mask/Sterile Medical Protective Mask |
| TYPE&SPECIFICATION | : | HL-KPTA,HL-KPTFA,HL-KFHA,HL-KFHFA |
| STANDARD APPLIED | : | PPE- (EU) 2016/425<br>EN149:2001+A1:2009<br>EN14683:2014 |

*The certificate of conformity is based on the evaluation of sample(s) of the above mentioned product on a voluntary basis.This is to confirm that the tested sample(s) is in conformity with the EC directive. It does not imply the assessment of the production of the product. The Holder is authorized to use the certificate in product will be deposited for 10 years after having stopped the production.*

*Notice of the CE marking:The label of the CE marking:Not less than 5mm heigt.Before putting the product(s) into market,CE marking and EC declaration are duties of the manufacturer.The manufacturer is responsible to start the CE marking certification procedure and to perform all the activities according to the Directive.*

Date Of Issue:
20th March 2020

Date Of Expire:
19th March 2025

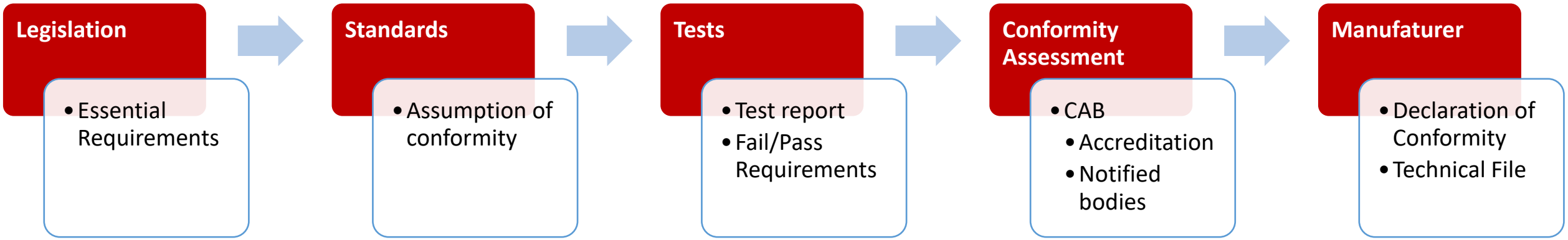
Authorised by

VÚBP

CE

**Výzkumný ústav bezpečnosti práce, v. v. i.**
Jeruzalémská 9
11652 Praha 1
Česká republika
Tel.: 221 015 844
Email : ao235@vubp-praha.cz
Website : www.vubp.cz

# Conformity Assessment Flow



# Contact

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