PRODUCTIP GUIDE FOR SUPPLYING THE EU MARKET WITH SURGICAL MASKS AND OR RESPIRATORY DEVICES

PROTECT THE PATIENT

SURGICAL MASK

MEDICAL DEVICE (MD) DIRECTIVE

EN 14683:2019+AC:2019

TYPE I, II or IIR

SELF CERTIFICATION

CE

REGISTER YOUR PRODUCT AT THE NATIONAL DATABASE!
(TO BE REPLACED BY EUDAMED IN 2021)

STERILE PRODUCT?

NOTIFIED BODY (NB) INVOLVED FOR PRODUCT TYPE APPROVAL AND MONITORING MASS PRODUCTION.
MANUFACTURER CERTIFIED TO ISO 13485

CE XXXX

XXXX IS FOUR-DIGIT NB ID

PROTECT THE HEALTH WORKER

RESPIRATORY DEVICE

PERSONAL PROTECTIVE EQUIPMENT (PPE) REGULATION

EN 149:2001+A1:2009

CLASS FFP2 or FFP3*

PRODUCT TYPE APPROVAL VIA NOTIFIED BODY (NB)

MASS PRODUCTION MONITORED BY NOTIFIED BODY

CE XXXX

XXXX IS FOUR-DIGIT NB ID

* CLASS FFP1 IS NOT RELEVANT FOR APPLICATION IN HOSPITALS REGARDING CORONA THEREFORE THIS TYPE IS NOT IN THIS OVERVIEW

A WORLD IN WHICH PRODUCTS CAN BE TRUSTED

PROTECT THE HEALTH WORKER AND THE PATIENT

COMBINATION OF SURGICAL MASK AND RESPIRATORY DEVICE FUNCTIONALITY

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A WORLD IN WHICH PRODUCTS CAN BE TRUSTED

Asking the question “Medical or not?” is ultimately incorrect, as both masks (SURGICAL MASKS approved to EN 14683 as well as RESPIRATORY PROTECTIVE DEVICES approved to EN 149) have suitable application in hospitals.
So what is going on? An overview!

SO WHAT IS THE STORY ABOUT SURGICAL MASKS?

Masks to EN 14683 intend to protect the one that is not wearing the mask. Medical staff wears it to protect the patient. They are often called surgical mask, the official name is medical face mask.

See also the scope of the EN 14683:

"This document specifies construction, design, performance requirements and test methods for medical face masks intended ***to limit the transmission of infective agents from staff to patients*** *during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier* ***can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms****."*

These masks to EN 14683 can be of Type I, Type II or Type IIR, according to bacterial filtration efficiency. The 'R' signifies splash resistance. The standard is a harmonised standard under the Medical Device Directive (*). Harmonised means that all EU Member States agree that it is relevant.

These masks are so-called non-invasive devices and these are in the Medical Device Directive classified as a class I device. Different classes have different conformity assessment schemes. In this case the conformity assessment scheme is based on module A; self-certification of the product design and of the mass produced goods.

Self-certification means that a company in the EU has to sign the so-called CE declaration. By signing this EU Declaration of Conformity as is its official name, they declare that the products placed on the market are meeting the requirements of the standard, and the essential requirements of the applicable legislation.

See the European Blue Guide (chapter 3) for who in the supply chain should do what.
https://ec.europa.eu/growth/content/‘blue-guide’-implementation-eu-product-rules-0_en

The product and packaging will have to carry;

- the CE marking
- a reference to the standard EN 14683
- the Type; I ,II or IIR
- article number
- name or trademark and address of the EU business entity placing the product on the market. The company that signed the CE declaration;
- traceability information / batch code
- to be used before date information

(Not intended to be a full detailed checklist)

It is recommended that the manufacturer (production site) is certified to EN ISO 13485.

If you want to offer these products as sterile you will have to involve a Notified Body. Of course this will impact production, packaging, markings and more.

- STERILE has to be added to the Type information.
- CE marking will be followed with the four-digit ID of the Notified Body involved in type testing the product and auditing the production.
- Manufacturer must be certified to EN ISO 13485

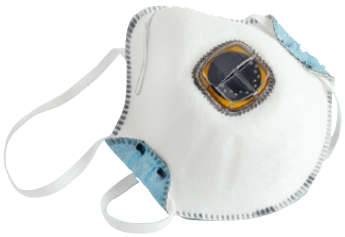
Sterile or not, ALL medical devices need to be registered with the national authorities! Each EU Member State has its own database.

This will be replaced in 2021 with a single EU registration at EUDAMED, an EU database that is part of the new Medical Device Regulation (MDR).

The implementation of the new Medical Device Regulation (MDR) is postponed to 2021. *https://ec.europa.eu/commission/presscorner/detail/en/ip_20_589*

A Notified Body (NB) is a testing institute appointed by an EU Member State. A testing institute can be a Notified Body for one or more Directives or Regulations. They all have a unique four-digit ID. For Medical Devices the Notified Bodies are located in the EU, Turkey, Switzerland and Australia only. You will find a complete overview of all the NB's on the EU Nando website: https://ec.europa.eu/growth/tools-databases/nando/

WHAT ABOUT THE OTHER MASKS?
THE SO-CALLED RESPIRATORY DEVICES OR PPE?



We wear them as a mask, but we should call them respiratory devices to avoid misunderstanding. Respiratory devices intend to protect the wearer. They are for personal protection and therefore in the scope of the Personal Protective Equipment (PPE) Regulation.

There are various types of respiratory devices. The design mostly relevant today are those approved to the, again a harmonised standard, EN 149. These come with an FFP1, FFP2 or FFP3 classification. FFP stands for: “Filtering Face-piece Particles”.

The scope of the EN-149 standard is:
*"This European Standard specifies minimum requirements for **filtering half masks as respiratory protective devices to protect against particles** except for escape purposes."*

The WHO, the World Health Organisation, mentions FFP2 or FFP3 types as the ones to be used by health workers during this COVID-19 crisis.

In this case the conformity assessment scheme for this kind of Personal Protective Equipment is based on module B for the design and C2 or even D for verification of mass produced goods. This means involvement of a Notified Body.

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Module B means that the design of the respiratory device has to be verified via a Notified Body (Type approval).

Module C2 or D means that a Notified Body has to verify compliance of the mass produced goods. This varies from random checks and audits to verification of the compliance of each shipment.

Conclusion, you cannot just buy some products and declare compliance by yourself. Not even based on testing by just some laboratory!

When you look for a supplier, note that the quality system of the manufacturer will be audited by a Notified Body. Perhaps you can find one that already has a certified quality system.

The final product and packaging will have

- a CE-marking, followed by the four-digit ID of the involved Notified Body.
- a reference to the standard EN 149
- a protection factor, in this case; FFP2 or FFP3
  followed with NR for single shift use
  followed with R for re-usable use
  when a D is added it means the device filters “dolomite” particles as well
- an article number
- an address of the EU business responsible for selling this product.
- traceability information / batch code
- “end of shelf life” date information

(Not intended to be a full detailed checklist)

Masks to EN 14683 are often called a surgical mask, and that might lead to the conclusion that only these types are medical. That is not correct.

Masks and respiratory devices, those that you also wear as a mask, are both used in hospitals, just a different application for different situations, dealing with different risks offering a different style of protection. Respiratory devices are also used in DIY and construction work as protection against dust.

A very common mistake is using a label and or packaging with an FFP classification, referring to EN 14683 and with a CE marking without a reference to a Notified Body. Clearly mixing things up. Totally wrong. Not the sign of confidence that you were looking for.

WHAT ABOUT THE COMBINATION?
SURGICAL MASK & RESPIRATORY DEVICE COMBINED!

A product with surgical mask Type II or Type IIR properties combined with respirator FFP2 or FFP3 properties is possible.

It combines the best of both worlds and is often used in hospitals.

This kind of product has to comply with the requirements of the EN 14683 as well as the EN 149 standard.

For the conformity assessment of the product the most rigorous regime will have to be followed. That is the one of the Personal Protective Equipment (PPE) Regulation. This means involvement of a Notified Body for checking that the design meets the requirements of the EN 149 standard, as well as for monitoring compliance of mass production.

For the EN 14683 part you still will have to self-declare compliance.

The final product and packaging will have

- a CE-marking, followed by the four-digit ID of the involved Notified Body.
- a reference to standard EN 14683 and Type I, II or IIR.
- a reference to the standard EN 149 and protection factor FFP2 or FFP3.
  followed with NR for single shift use
  followed with R for re-usable use
  when a D is added it means the device filters “dolomite” particles as well
- article number
- address of the EU business responsible for selling this product.
- traceability information / batch code
- “end of shelf life” date information

(Not intended to be a full detailed checklist)

Because of the compliance with EN 14683 it is a medical device and you need to register it at one of the national databases

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At ProductIP we do know these things. Because it is our daily job.

As the situation is changing continuously this information by ProductIP is

- general and is not intended to address the specific circumstances of any particular individual or entity.
- not necessarily comprehensive and complete.
- sometimes referring to actions of external actors over which we have no control and for which we cannot assume responsibility.
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These technical files enable you to demonstrate to authorities, consumers, other stakeholders, that you are in control of product compliance in a way that is in line with the regulatory framework.

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FAQ - SURGICAL MASKS

1 Now that the situation requires an urgent supply of medical, surgical masks, can you sell them even before you have CE?

No. You must ensure that the design of the products complies with the requirement and that mass produced items are as per original design. It is self-certification like many other non-food consumer products.

2 Are other international types of surgical masks interchangeable?

So far we found only these

- The US refers to ASTM2100 as a standard Specification for Performance of Materials Used in Medical Face Masks
- The Chinese standards we found are GB 19083-2010 Technical Requirements for Protective Face Mask for Medical Use and YY 0469-2011 Surgical Masks

There are substantial differences, and these do require additional tests if you want to sell these masks on the European market. One may assume that a manufacturer that can produce a product to a standard for one market would be able to deal with similar requirements for another market.

3 Do we need to register medical devices before we can sell them?

All medical devices need to be registered with the national authorities! Each EU Member State has its own database!

This will be replaced in 2021 with a single EU registration at EUDAMED, an EU database that is part of the new Medical Device Regulation (MDR).

The implementation of the new Medical Device Regulation (MDR) is postponed to 2021.
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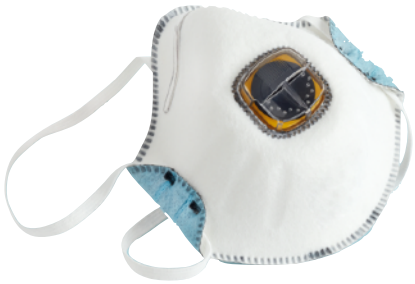
FAQ - RESPIRATORY DEVICES



4 Now that the situation requires an urgent supply of the respiratory devices, can you sell them even before you have CE via the Notified Body route?

Yes, there are alternative intermediate routes available while approval via a Notified Body is pending! This route does come with obligations! These routes are for the market for health workers use only. See FAQ number 6 for more details about the available routes.

5 Are other international types of respiratory devices interchangeable?

International respiratory devices similar to the EU FFP2 type are;

- US type N95 (NIOSH-42CFR84)
- Chinese type KN95 (GB262-2006)
- Australian/New Zealand type P2 (AS/NZA 1716:2012)
- Korean type 1st class (KMOEL - 2017-64)
- Japanese type DS (JMHLW-Notification 214,2018)

Choosing a similar type does not mean you can access the European market immediately! There are substantial differences between the various national requirements, and these do require additional tests. One may assume that a manufacturer that can produce a product to a standard for one market would be able to deal with similar requirements for another market.

6 Do FFP respiratory devices always have a valve?

No. There are also types without. Example FFP2 type 8810 by 3M

(3M has not been involved in any way in the making of this guide)

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FAQ

7 What are the routes to the market?

Currently there are two routes

Route 1 **The Regular Route**

Full approval of the product and production site by a Notified Body to EN 149.
Monitoring of conformity of mass production via a Notified Body.
Product, packaging, all have the correct marking. Distribution into the EU market.
Registration at the various national databases for medical devices in case the product also has approval to EN 14683

Route 2 **The alternative route currently available**

LIMITED TO SUPPLY FOR HEALTH WORKERS USE ONLY!

- Start application of approval of the product to EN 149 as well as of the production site by a Notified Body
- Collect documentation of the current approved product and QC system of the factory
- Ensure that you have sufficient samples available.
- Contact your EU national market surveillance authority and ask for evaluation of the product in order to obtain permission to supply the products for health workers use pending final approval by the Notified Body of product and production site.
- Product, Packaging, might have incomplete markings when it comes to brandname and EU address. This can be acceptable (final judgement by the authorities) because the distribution will be organised towards health workers only. This limits potential traceability risk.
- Of course the mentioning of the FFP classification on the product has to be clear. Otherwise the health workers cannot choose the right product for the right application.
- In case of the combination product; Mask to EN 14683 and Respiratory Device to EN-149 the product might even only have a CE marking without the reference to a Notified Body, as that approval process is still pending.

This alternative route is made clear in EU 2020/403
https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32020H0403

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FAQ

8 Can a product be a surgical mask as well as a respiratory device?

Yes it is possible to have a product that is compliant with both the EN 14863 and EN 149 at the same time. For such a product there are two certification routes applicable in parallel. This is described on page 7 of this document.

9 Is there no need to register respiratory devices in the medical databases?

That is correct. Only medical devices have to be registered. In these examples that means:
- surgical masks compliant with the standard EN 14683, or
- masks compliant with both the EN 14683 and the EN-149 standard,
have to be registered.

Respiratory devices only compliant with the EN 149 cannot be registered.

10 Why involvement of a Notified Body for a respiratory device (EN 149) ?

The answers are given in the PPE Regulation (EU) 2016/425.

PPE products intended for the protection of the respiratory system of the wearer are Category III. Article 19 of the PPE Regulation defines the following conformity assessment procedures for Category III:
- Always EU type-examination (module B)

  plus either of the following:

- internal production control plus supervised product checks at random intervals (module C2);
- quality assurance of the production process (module D).

Details on the modules are also given in the PPE Regulation Annexes V, VII and VIII. The CE marking on the product shall be followed by the identification number of the notified body involved in module C2 or D.

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11 Is there a special symbol for indicating shelf life?

You should use the ISO 7000-2607 symbol for “Use by date”

in combination with mm/yy or mm/yyyy

12 How can i see if the certificate is for product or production (PPE / EN 149) ?

The certificate for the Notified Body’s product approval will refer to Module B of the PPE Regulation. In most cases the title will be EU-TYPE EXAMINATION CERTIFICATE; it will mention the product reference.

The certificate for the conformity of production will refer to Module D of the PPE Regulation; it will mention the factory location.

13 Is there a ISO standard for the quality assurance of factories producing PPE, like ISO 13486 for factories producing products under the Medical Directive?

No. There is no specific ISO standard for quality assurance for the production of Personal Protective Equipment.

14 Do I need a specific laboratorium to test products to EN 14683?

No. You do not need a specific laboratory or Notified Body to test a Class 1 medical device. Exception is; if you want to sell STERILE masks approved to EN 14683 you must involve a Notified Body.

In general we do advise to verify if the laboratorium is accredited and that the tests you want them to carry out are in the scope of their accreditation,

15 I am selling surgical masks (EN 14683) under my own brand name. Do I need an European Authorised (EU AR) representative?

When you are selling products in Europe (placing products on the market) under your own brand you will automatically have all the obligations of a manufacturer. If you are in the EU your name and address will have to be mentioned. If you are a brand-owner outside the EU you must appoint an EU AR. (EU representative)

FAQ

16 Is there a special symbol to inform endusers about accompanying instructions?

Yes. You should use ISO symbol 7000-1641 on medical devices and personal protective equipment to point the enduser to additional instructions

17 What about fake certificates?

As with any other product there is always a risk of running into fake certificates. Combine the opportunities to make money with the pressure to make money and ….

That is why many companies in retail and trade use our platform and our expert team to collect and review documentation. Especially when it concerns both and new suppliers and high risk products. Building up a technical file is a stress test for the performance of the supply chain partners. Well organised businesses will have no problem to fill in the key elements. Supply partners should not struggle having the essential information on hand!

The European Safety Federation (ESF - trade organisation of suppliers of PPE) , has collected various examples of where it went wrong.

https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe

What can you do?
Check the issuing lab especially if it doesn't sound familiar
- accreditation
- website looks reliable and up-to-date or …
- google street-view, does this match with pictures on the website?
- do they have a phone number ? Call

Always or call or do an online check and verify if the issued document is valid for the products mentioned on it, in relation to the company name to which the document has been issued.

FAQ

18 Do you need to add the EU DoC for PPE products (EN 149)?

Either you add the EU DoC (The CE Declaration of Conformity) to each box or you refer clearly to the webpage where it can be accessed.

Note: ProductIP users can activate the public page for a technical file and highlight the related document as “available for public”. The URL will be available for 10 years.

19 Do you need to add the EU DoC for Medical Devices (EN 14683)?

No. It need to be available per request of the market surveillance authorities. Registration of Medical Devices is mandatory. This moment in the national register of each Member State.

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