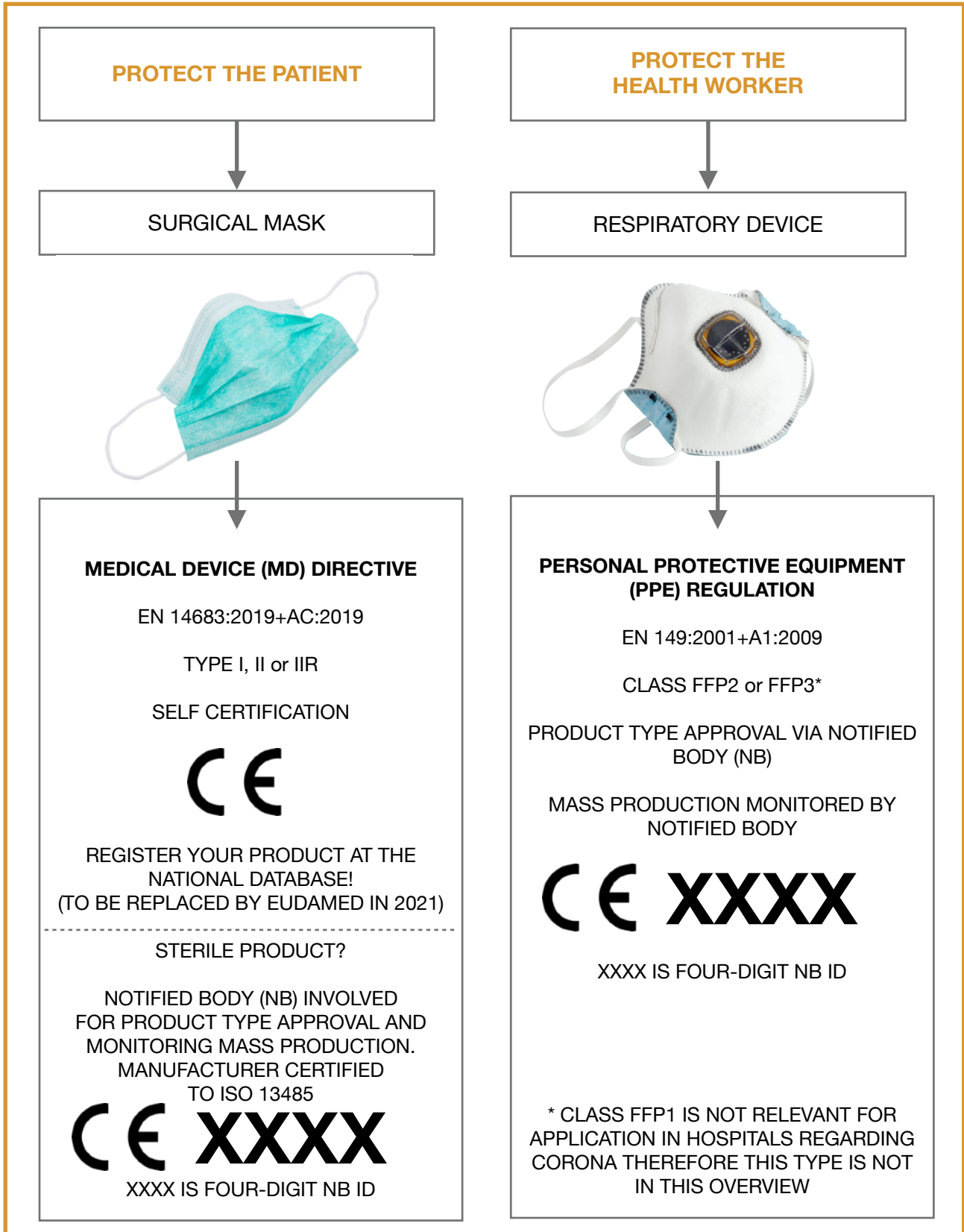


PRODUCTIP GUIDE FOR SUPPLYING THE EU MARKET WITH SURGICAL MASKS AND OR RESPIRATORY DEVICES



PROTECT THE HEALTH WORKER AND THE PATIENT

COMBINATION OF SURGICAL MASK AND RESPIRATORY DEVICE FUNCTIONALITY



MEDICAL DEVICE (MD) DIRECTIVE

EN 14683:2019+AC:2019

TYPE I, II or IIR

SELF CERTIFICATION

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

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

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

CE XXXX

XXXX IS FOUR-DIGIT NB ID

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

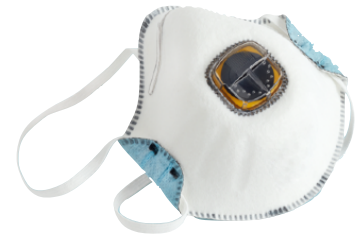
Sterile or not, ALL medical devices need to be registered with the national authorities! Each EU Member State has its own database.

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. 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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HOW DO WE KNOW THESE THINGS?

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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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?

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).

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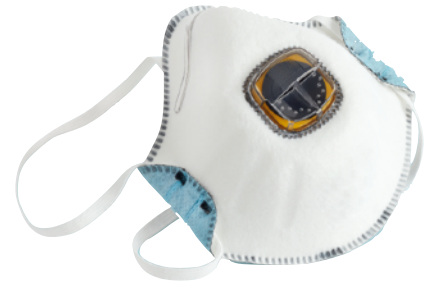
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FAQ - RESPIRATORY DEVICES



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.

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FAQ

6 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

7 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.

8 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.

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