NSAI

Coronavirus COVID-19 National Programme

Quick Guide to manufacturing and importing Personal Protective Equipment and Medical Devices

for the COVID-19 pandemic to ensure compliance

Table of Contents

1. Introduction

Personal Protective Equipment (PPE) or Medical Devices (MD) may not be placed on the market or brought into service in Ireland unless they comply with essential health and safety requirements for PPE, and safety and performance requirements for Medical Devices.

CE marking indicates that the product is deemed to be in conformity with the regulations/directives.

The means to gain product approval and CE marking of a product can be achieved by the application of European harmonised standards (often referred to as technical/ alternative solutions).

Depending on the product that you intend to manufacture, you should check the European standard or other technical solution to determine the performance requirements, testing etc required. At the same time, you should contact a notified body (otherwise known as a third-party testing body or conformity assessment body) for assistance, notified bodies are an essential part of the conformity assessment process leading to CE marking. The notified body will assess the device to ensure it conforms with the requirements of the relevant directive or regulation. Following completion of testing, the manufacturer is required to maintain a technical documentation compliant with the relevant regulations and directives.

If you are manufacturing a PPE or Medical Devices product in response to the COVID-19 pandemic, the European Commission has published guidelines related to CE marking your product. You should contact the applicable national market surveillance authority to discuss the derogation procedure for placing non CE marked devices on the national market.

If you intend to import PPE and/or Medical Devices for sale or distribution in Ireland, you have responsibilities and obligations, please refer to the Regulation or Directive for the obligations of economic operators.

2. Roadmap for Placing Products on the Market

If you intend to put Medical Devices or Personal Protective Equipment on the market, there are a number of steps you need to do.

1. Identify if the product is classified as Personal Protective Equipment (PPE) or Medical Device (MD)
2. Identify the applicable Regulation or Directive to which compliance is required
3. Identify the applicable standards (technical solution)
4. Identify if testing is required for the product to be placed on the market
5. Identify a notified body that is designated for your product type and contact them to discuss the conformity assessment pathway, if applicable
6. Check the need to register your product with a National Competent Authority

3. PPE

3.1 What is PPE?

Personal protective equipment is any device or appliance that is worn or held by an individual for the protection against one or more health and safety hazards.

Examples of PPE that may be used in the current COVID-19 response:

- Facemasks
- Gloves
- Protective eyewear
- Protective coveralls

3.2 What EU legal framework applies to PPE?

PPE regulation **EU 2016/425** was adopted in 2018 under statutory instrument (S.I. 136) of 2018.

3.3 Does NSAI certify Personal Protective Equipment?

No, NSAI is not designated to certify (conformity assessment) for PPE.

Click **here** to be redirected to the EU NANDO website for a list of notified bodies designated under the PPE regulation 2016/425.

For a list of notified bodies designated to certify the products below, click the link:

- **Equipment providing Face protection**
- **Equipment providing Eye protection**
- **Equipment providing Respiratory protection**

3.4 Who is the National Market Surveillance authority for PPE (Competent Authority)?

The Health and Safety Authority (HSA). Contact: **wcu@hsa.ie**

Note: A Competent Authority is appointed by the Member State to perform a designated function and given the necessary powers for enforcement etc.

4. Medical Devices

4.1 What is a Medical Device?

A Medical Device is any instrument, apparatus, appliance, software, implant, re agent, material or other article intended by the manufacturer to be used alone or in combination for human beings for one or more of the following medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- Providing information by means of in vivo examination of specimens derived from the human body including organ, blood and tissue donations

And which does not achieve its principal intended action by pharmacological, immunological or metabolic means in or on the Human body, but which may be assisted in its function by such means.

Examples of Medical Device that may be used in the current COVID-19 response:

- Surgical masks
- Medical gloves
- Surgical drapes and gowns
- Ventilators
- Nebulisers

4.2 What EU legal framework applies to Medical Devices?

Council Directive **93/42/EEC** (MDD) to be replaced by **Regulation (EU) 2017/745** (MDR) on the 26th May 2020.

The Commission has adopted a proposal to postpone the application date of the new MDR for one year. This has been adopted by the European Council and Parliament ratifying the postponement of the application date for Regulation (EU)2017/745 for one year, until 26th of May 2021.

For more information see the **European Commission website**.

4.3 Does NSAI certify medical devices?

Yes, NSAI is designated to certify Medical Devices, Active Implantable Devices and In Vitro Diagnostic Devices.

Contact **Colm.ORourke@nsai.ie** for more information.

4.4 Who is the national market surveillance authority for medical devices (Competent Authority)?

The **Health Products Regulatory Authority** (HPRA).

5. Other Important Information

5.1 What standards should be applied to produce certain PPE and Medical Devices?

Harmonised standards give presumption of conformity to certain essential requirements within the PPE regulation, the Medical Device directive and the general safety and performance requirements of the Medical Device's regulation. In response to the COVID-19 Crisis, NSAI is providing access to a number of relevant standards for PPE and Medical Devices. To access these standards without charge, click on the following link and follow the instructions:

COVID-19 Standards package

Link to the full list of harmonised standards for PPE and Medical Devices are provided below, some of which are provided free in the previous link.

Regulation EU 2016/425 **PPE Harmonised standards**

Directive 93/42/EEC - Medical device harmonised standards

5.2 Is there an alternative to the use of Standards?

The World Health Organisation guidelines for choice of personal protective equipment provide a **list** of alternative technical solutions that may be adopted by the manufacturer, where these alternative technical solutions are used a sample of the product should be tested by a notified body (a third party testing body) in the case of products falling within the PPE regulation.

5.3 Does NSAI perform Type testing for PPE or Medical Devices?

No, NSAI does not perform type testing for PPE or Medical Devices. Please click **here** for a list of European laboratories which are accredited for the scope.

Click on the ILAC link **here** for a list of globally recognised accreditation bodies if you need to determine if a test certificate is acceptable.

5.4 Obligations of the Importer and/or Distributor

Under the applicable regulations/directives, the importer and/or distributor in this context are referred to as an economic operator. The economic operator established in the European Union is one who places a product from a third country on the market for the first time. Their responsibilities and obligations are described in the relevant Regulations and Directives.

5.5 NSAI Contacts

For further information please contact **COVID-19-support@nsai.ie**.

5.6 European Commission recommendations and guidance

For further information the European commission has produced a number of guidance documents in relation to the **COVID-19**:

- Please click here to be redirected to the European commission page on **PPE**
- A guidance on medical devices, active implantable devices and in vitro diagnostic devices in the **COVID-19 crisis**
- A guidance document on conformity **assessment for PPE**
- A questions and answers on increased production of safe medical **supplies**
- FAQ in relation to **protective equipment**
- Recommendations on conformity assessment and market surveillance procedures within the context of **COVID-19 crisis**

5.7 Additional reference links that may be useful for information

- Information on accredited labs for **facemask testing**
- **Comparison of standards** for medical protection products between China and European by SAC

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