AWTORITÀ TA' MALTA GĦALL-KOMPETIZZJONI U GĦALL-AFFARIJIET TAL-KONSUMATUR
Mizzi House, Triq Nazzjonali,
Blata l-Bajda, ĦMR9010,
Malta.

MCCAA
MALTA COMPETITION AND CONSUMER AFFAIRS AUTHORITY

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Mizzi House, Triq Nazzjonali,
Blata l-Bajda, ĦMR9010,
Malta.

Our Ref. PPE 2018/03

Your Ref.

Tel : (+356) 23952000

Email : info@mccaa.org.mt

Explanatory Notes

1. Introduction

Title of regulations	Personal Protective Equipment (Implementing Measures) Regulations, 2018
Activity to be regulated	These regulations implement the requirements set out in Regulation (EU) 2016/425 in order to ensure that personal protective equipment on the European market provides the highest level of protection against hazards.
Responsible entity	The Technical Regulations Division (TRD) within the Malta Competition and Consumer Affairs Authority (MCCAA)

2. Summary and background

2.1 Aims & Objectives of the legislation

These proposed regulations implement the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (the "Regulation").

The Regulation may be accessed through the following link:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0425

The objective of the Regulation is namely to ensure that equipment on the market fulfil the requirements established therein, providing for a high level of protection of health and safety of users and to allow the equipment to be sold and used throughout the European Union.

2.2 Importance of regulations

Although the Regulation is directly applicable and therefore as such requires no implementation, certain aspects thereof still depend on Member States for their activation. The current regulations seek precisely to adopt the implementing provisions which are necessary for the effective functionality of the Regulation.

The Regulation itself, requires PPE which are covered by its scope, to be designed and manufactured in accordance with the essential requirements listed therein. The Regulation also establishes rules

designed to achieve the free movement of PPE in the internal market.

2.3 Public Consultation

Interested parties are invited to submit comments on the draft legal notice by **13th April 2018**.

3. Overview of the structure of the instrument

The current legal notice consists of 5 articles, implementing the requirements set out in Regulation (EU) 2016/425.

More specifically, article 3 of the regulations establishes *The Technical Regulations Division within the Malta Competition and Consumer Affairs Authority* as the "notifying authority", within the meaning of Article 21 of the Regulation.

Article 2(2) regulates the assessment and notification of conformity assessment bodies as well as the monitoring of notified bodies, stipulating that the procedures in relation thereto shall be those laid down in the Method for Designating Conformity Assessment Bodies Regulations[1].

Article 4 then establishes the penalties for infringements, while article 2(3) relates to the use of either Maltese or English in relation to certain requirements stipulated in the Regulation.

Article 5 of the new regulations, furthermore, repeals the provisions of the Personal Protective Equipment Regulations[2] with effect from 21 April 2018.

The proposed Legal Notice is therefore important because it adopts the implementing requirements which are necessary to bring about the effective functionality of the Regulation.

In so far as the Regulation itself is concerned, this starts out primarily by stipulating its scope, stating that it applies to "personal protective equipment" (PPE). The Regulation then lists a series of definitions that need to be taken into account in order to fully understand its provisions. Subsequently, the Regulation sets out requirements regulating the making available on the market of PPE covered by the scope of the Regulation and ensuring that such making available on the market is not restricted, hindered and prohibited whenever PPE comply with the Regulation.

The Regulation then sets requirements by placing certain obligations on economic operators related to manufacturers, authorised representatives, importers and distributors. The Regulation also lists the requirements and procedures in which PPE conform to the applicable harmonised standards.

The Regulation lists a number of provisions concerning the conformity of PPE with the Regulation, in particular the appropriate conformity assessment procedure to be followed by the manufacturer, and rules governing the affixing of the CE mark on PPE, indicating their compliance with the Regulation.

[1] Subsidiary Legislation 427.45.
[2] Subsidiary Legislation 427.38.

Annex I lays down the three main categories of risks against which PPE is intended to protect users.

Annex II contains the list of essential health and safety requirements that must be satisfied by PPE falling within the scope of the Regulation.

Annex III stipulates the minimum elements to be listed in technical documentation by the manufacturer to ensure the PPE conforms to Annex II.

Annex IV lists sets out the conformity assessment procedure whereby the manufacturer ensures and declares that the PPE satisfies the applicable requirements of the Regulation.

Annex V to VIII sets out the conformity assessment procedures by which a notified body checks that PPE fulfils the essential health and safety requirements stipulated by the Regulation.

Annex IX lists the required content of the EU declaration of conformity of the PPE.

4. Commentary on parts and articles of the Regulation.

Regulation Article No.	**Meaning & obligations placed on user**
4 – Making available on the market	This article entails that PPE shall be made available on the market only if it complies with the Regulation.
5 – Essential health and safety requirements	PPE shall meet the essential health and safety requirements stipulated in Annex II of the Regulation.
8 – Obligations of manufacturers	This article stipulates the obligations for manufacturers of PPE that are covered by the scope of the Regulation. (1) Manufacturers shall ensure that PPE have been designed and manufactured in accordance with Annex II. (2) Manufacturers shall draw up the technical documentation and carry out the relevant conformity assessment procedure or have it carried out. (3) Where compliance has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, and affix the CE marking. (4) The manufacturer shall keep the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the

	market. (5) Manufacturers shall ensure that procedures are in place for series production. Changes in product design or characteristics and changes in the harmonised standards shall be adequately taken into account. (6) With regard to the risks, manufacturers shall carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring. (7) Manufacturers shall ensure that their PPE bear a type, batch or serial number or other element allowing its identification. (8) Manufacturers shall indicate on the PPE their name, registered trade name/mark and the contact address. (9) Manufacturers shall ensure that the PPE is accompanied by the instructions and information in the Maltese or English language. Instructions, information and labelling shall be clear, understandable, intelligible and legible. (10) The manufacturer shall provide the EU declaration of conformity with the PPE or include the necessary information and instructions and the internet address from which it can be accessed. (11) Manufacturers who consider that PPE which they have placed on the market is not in conformity with the Regulation shall bring that PPE into conformity, to withdraw it, or to recall it, and inform the Technical Regulations Division. (12) Manufacturers shall, further to a reasoned request from the Technical Regulations Division, cooperate and provide it with all the information to demonstrate the conformity of the PPE.
9 – Authorised representatives	This article stipulates that an authorised representative shall keep the EU declaration of conformity, and the technical documentation for 10 years. It also requires them to cooperate and present all the necessary information to the Technical Regulations Division.
10 – Obligations of importers	This article stipulates the obligations for importers of PPE that are covered by the scope of the Regulation. (1) Importers shall place only compliant PPE on the market. (2) Importers shall ensure that the manufacturer has done the appropriate

	conformity assessment procedure, has drawn up the technical documentation, PPE bears the CE marking, and is accompanied by a copy of the EU declaration of conformity and the required documents. (3) Where an importer considers or has reason to believe that PPE is not safe, he shall not place it on the market until it has been brought into conformity, and shall inform the manufacturer and the market surveillance authorities to that effect. (4) Importers shall indicate on the PPE their name, registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the PPE. (5) Importers shall ensure that the PPE is accompanied by the instructions in Maltese or English language. (6) Importers shall ensure that its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements. (7) When deemed appropriate, importers shall carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring. (8) Importers who consider that PPE which they have placed on the market is not in conformity with the Regulation shall bring the PPE into conformity, to withdraw it or recall it, and inform the Technical Regulations Division. (9) Importers shall, keep a copy of the EU declaration of conformity for 10 years after the PPE has been placed on the market at the disposal of the market surveillance authorities, upon request. (10) Importers shall, further to a reasoned request from the Technical Regulations Division, cooperate and provide it with all the information and documentation to demonstrate the conformity of PPE.
11 – Obligations of distributors	This article stipulates the obligations for distributors of PPE that are covered by the scope of the Regulation. (1) Distributors shall verify that PPE bears the CE marking and that is accompanied by the instructions and information in the Maltese or English language. (2) Where a distributor considers or has reason to believe that PPE is not safe, he shall not make it available on the market until it has been brought into conformity, and shall inform the manufacturer or the importer and the

	market surveillance authorities to that effect. (3) Distributors shall ensure that its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements. (4) Distributors who consider that PPE which they have made available on the market is not in conformity with the Regulation shall bring that PPE into conformity, to withdraw it or recall it, and inform the Technical Regulations Division. (5) Distributors shall, further to a reasoned request from the Technical Regulations Division, cooperate and provide it with all the information and documentation to demonstrate the conformity of the PPE.
12 - Cases in which obligations of manufacturers apply to importers and distributors	This article stipulates that when an importer or distributor places PPE on the market under his name or trademark or modifies it in a way that compliance with this Regulation may be affected, shall be considered a manufacturer.
13 - Identification of economic operators	This article requires economic operators to keep a record of those economic operators who have supplied them with the PPE or to whom they have supplied the PPE. It also requires them to present such information to the Technical Regulations Division.
14 – Presumption of conformity of PPE	This article stipulates that PPE which is in conformity with the harmonised standards shall be presumed to be in conformity with the essential health and safety requirements set out in the Regulation.
15 - EU declaration of conformity	This article stipulates requirements related to the EU Declaration of Conformity as specified in the following: (1) The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements has been demonstrated. (2) The EU declaration of conformity shall have the model structure, shall contain the elements specified in the relevant modules in the Maltese and English language, and shall be continuously updated. (3) In case that PPE is subjected to more than one Union act, a single EU declaration of conformity shall be drawn up in respect of such Union acts. (4) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the PPE.

17 – Rules and conditions for affixing the CE marking	This article contains requirements relating to the CE marking as specified in the following: (1) The CE marking shall be affixed visibly, legibly and indelibly to the PPE. (2) The CE marking shall be affixed before the PPE is placed on the market. (3) The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative. (4) The CE marking and identification number may be followed by a pictogram or other marking indicating the risk against which it is intended to protect.
19 - Conformity assessment procedures	This article lists the conformity assessment procedures to be followed according to the risk categories set out in Annex I.

5. Concluding Section

These regulations and the Regulation shall apply as from **21st April 2018**.

N.B. This Explanatory Note is not intended to be an exhaustive description of the instrument nor a substitute thereof or a legislative supplement to it. This Note does not purport to be an authoritative ruling on the interpretation of the legislation.