

1. -----IND- 2017 0533 DK- EN- ----- 20171130 --- --- PROJET

13 October 2017

## DRAFT

### Order on the design etc. of personal protective equipment<sup>1) 2)</sup>

*(Additional requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment)*

The following is laid down pursuant to § 3a(2), § 20, § 21(1) and § 27(4) of Act No 155 of 20 February 2013 on the design etc. of certain products, as amended by Act No XX of XX, and by authorisation under § 22:

#### *Scope*

**§ 1.** This order implements certain parts 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 (hereinafter 'Regulation (EU) 2016/425').

**§ 2.** The order applies to personal protective equipment as defined and specified in Articles 1-3 of Regulation (EU) 2016/425.

**§ 3.** The order applies to manufacturers, their representatives, importers, distributors, notified bodies and other entities as stipulated by Regulation (EU) 2016/425.

#### *General provisions*

**§ 4.** Personal protective equipment may be placed or made available on the market only if it complies with the requirements of Regulation (EU) 2016/425 and the additional requirements stated in this order.

*Paragraph 2.* Manufacturers, their representatives, importers, distributors, notified bodies and other entities, as stipulated by the regulation, must comply with the requirements laid down in this order.

**§ 5.** Personal protective equipment may be placed or made available on the market only if:

- 1) the EU declaration of conformity is drawn up in or translated into Danish (see Article 15(2) of Regulation (EU) 2016/425), and
- 2) the instructions and the information referred to in Annex II, point 1.4 of Regulation (EU) 2016/424 is drawn up in or translated into Danish (see Article 8(7), Article 10(4) and Article 11(2) of Regulation (EU) 2016/425).

#### *Notified bodies*

**§ 6.** The director of the Danish Working Environment Authority may designate notified bodies (see Article 21 of Regulation (EU) 2016/425).

*Paragraph 2.* In order to be designated as a notified body, the applicant must be accredited by DANAK - The Danish Accreditation Fund (cf. the Order on the designation of the national accreditation body).

*Paragraph 3.* Accreditation in accordance with paragraph 2 must be related to the task for which designation is applied, and it must be ensured that the requirements of Article 24 of Regulation (EU) 2016/425 are complied with.

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1 ) This order incorporates certain provisions 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 (OJ L 81, 31.3.2016, p. 51). According to Article 288 of the Treaty on the Functioning of the European Union, a regulation shall be directly applicable in all Member States. The reproduction of these provisions in the Order is therefore exclusively for practical reasons and does not affect the direct application of the regulations in Denmark.

2 ) This order has been notified as a draft in accordance with Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification).

*Paragraph 4.* In order to be designated as a notified body, the applicant must also comply with the requirements of Articles 26, 32-34 and 36(2) of Regulation (EU) 2016/425.

*Paragraph 5.* DANAK - The Danish Accreditation Fund shall assess whether the applicant complies with the requirements for designation (cf. paragraphs 2-4) and shall monitor the notified bodies' continued compliance with the designation requirements.

*Paragraph 6.* The Danish Working Environment Authority may check and monitor the notified bodies' continued compliance with the designation requirements; cf. paragraphs 2-4. The notified body must, on request, provide all relevant information.

*Paragraph 7.* The director of the Danish Working Environment Authority may withdraw the notified body's authorisation if it no longer meets the criteria for the authorisation referred to in paragraphs 2-4.

#### *Appeals*

**§ 7.** Appeals against decisions made under this order may not be lodged with another administrative authority, subject to § 8.

**§ 8.** Appeals against decisions made by notified bodies may be lodged with the Danish Working Environment Authority within 4 weeks after the decision was made known to the person concerned.

#### *Penalties*

**§ 9.** Unless a more severe penalty is to be imposed pursuant to the Act on the design etc. of certain products or other legislation, a fine will be imposed on anyone who

- 1) violates §§ 4 and 5, or provisions of Regulation (EU) 2016/425, or
- 2) fails to comply with decisions, including injunctions or bans issued in relation to provisions of this order or Regulation (EU) 2016/425.

*Paragraph 2.* Entities, etc. (legal persons) may be made criminally liable in accordance with the regulations in Chapter 5 of the Penal Code.

#### *Entry into force and transitional provisions*

**§ 10.** The order shall enter into force on 21 March 2018, subject to paragraphs 2 and 3.

*Paragraph 2.* The order applies to personal protective equipment that is placed or made available on the market from 21 April 2018, subject to paragraph 3. The current rules apply to personal protective equipment placed or made available on the market or put into use before 21 April 2018.

*Paragraph 3.* Personal protective equipment may still be made available on the market if it is made available in accordance with Order 683 of 10 June 2013 on the design etc. of personal protective equipment prior to 21 April 2019.

*Paragraph 4.* On 21 April 2019, Order No 683 of 10 June 2013 on the design etc. of personal protective equipment shall be repealed.

*The Danish Working Environment Authority, [DATE]*

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