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**Accreditation as basis for notification**

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## 1. Application

**1.1** This accreditation regulation contains requirements for companies (laboratories, certification and inspection bodies) where a DANAK accreditation is the basis for being appointed as notified body in accordance with EU legislation.

**1.2** It is stated in Regulation (EC) No 765/2008, article 5 *Operation of accreditation* and decision 768/2008, article R 22 *Application for notification*, that an accreditation certificate (decision on accreditation) can be used as documentation for meeting requirements in relevant EU legislation (directives, regulations etc.)

**1.3** It is stated in executive orders whether there in Denmark are requirements for accreditation as basis for being notified and which requirements in directives and regulations are to be assessed during accreditation.

## 2. Application on accreditation and extension

**2.1** When applying for accreditation or extension of accreditation for notification it shall be stated which EU-directive or regulation the accreditation shall declare conformity with.

**2.2** European Accreditation (EA) has issued EA-2/17:2016 - *EA Document on accreditation for notification purposes*. DANAK will use this document at the assessment, when accreditation shall be used as basis for appointment as notified body.

**2.3** Table 1 in EA-2/17 contains a list of accreditation standards to be used for the different types of conformity. It is here stated that additional requirements may apply from other standards apart from the one accredited to (for instance ISO 17065), when the scheme include activities related to other standards (e.g. ISO 17021-1). Fulfilment of these additional requirements in other accreditation standards shall be stated in the accredited company's management system.

**2.4** Table 2 and 3 in EA-2/17 is a list of preferred accreditation standards for the different types of conformity. New applicants shall apply for accreditation for the preferred standards, unless otherwise stated by the notifying authority. Existing accreditations can be transferred to the preferred standards if agreed upon with the notifying authority.

**2.5** The application shall be accompanied by documentation for fulfilment of all requirements to the notified body in the EU directive or regulation. The requirements stated in the EU documents which are to be fulfilled through accreditation will often appear in a Danish executive order on implementation. It shall be clearly stated in the application if there are requirements to the notified body in the directive/regulation not stated in the executive order, which are requested not to be assessed by accreditation. It will be stated in the accreditation certificate (decision and accreditation certificate) that these requirements are not assessed.

**2.6** The application shall specify the extent of accreditation by indication of e.g. directives, regulations, harmonised standards, product areas, modules. The specification shall follow the layout of the EU Commission database of notified bodies, NANDO or a database relevant for the area.

**2.7** It shall be clearly stated in the application if the accreditation is to be used as basis for notification of an area not yet specified in a relevant database.

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**2.8** The company shall keep updated with interpretations from the sector groups for notified bodies mentioned in EU documents relevant for the applied accreditation scope and it shall be stated in the management system of the company how interpretations are being implemented.

**3. Maintaining accreditation**

**3.1** Accredited companies using accreditation as basis for a notification shall continuously ensure that no notified work is carried out according to standards or specifications, not enlisted as the harmonised basis in Nando or a database for the relevant area.

**3.2** In case new normative documents specifying an accreditation c.f. item 2.5 are published the accredited company shall apply for extension or change of their accreditation accordingly, before accredited or notified work is carried out.

**3.3** Accredited companies shall continuously ensure compliance with item 2.3, 2.5 and 2.8

**4. References**

Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products.

Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products.

EA-2/17: *EA Document on Accreditation for Notification Purposes.*

This accreditation regulation comes in to force 23 November 2017. Any differences between the Danish and the English version of this document are not intended, but in case of doubt with respect to the correctness the Danish version should be consulted