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Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

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1 Introduction

Article 16(3) of Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) introduces requirements on the quality management system to be established by distributors and importers[1] carrying out any of the activities mentioned in points (a)[2] and (b)[3] of Article 16(2) concerning relabelling and repackaging of devices[4].

Article 16(4) of the MDR / IVDR provides for a notified body to certify that the quality management system of the distributor or importer complies with the requirements laid down in the abovementioned Article 16(3).

Notified bodies providing such certifications are required to be designated for the type of devices that are subject to activities mentioned in points (a) and (b) of Article 16(2). However, such certification activities to be performed by them are not related to conformity assessment activities carried out to certify manufacturer's devices according to either Article 52 of the MDR or Article 48 of the IVDR. Therefore, notified bodies need to establish the assessment activities necessary in order to certify the quality management system of a distributor or importer intended to relabel and / or repackage a device. In addition, it is also important to get clarity on the elements to be addressed by distributors and importers in the abovementioned quality management system.

This guidance document is mainly focused on activities performed by notified bodies, providing also clarification on the quality management system they are expected to assess.

A separate MDCG guidance document, in the form of Questions & Answers, is being developed to complement and address implementation of other relevant requirements for distributors and importers introduced by Article 16 of MDR / IVDR.

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1 "Other natural or legal persons" referred to in Article 16(1) are not subject to paragraphs (3) and (4) of Article 16.

2 *(a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;*

3 *(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.*

4 For the purpose of this guidance document, references to relabelling or repackaging activities do also include instructions for use.

2 Scope

This guidance is intended to provide assistance to notified bodies to implement requirements established by MDR and IVDR with regard to certification activities to be carried out according to Article 16(4), attesting that the quality management system of the distributor or importer carrying out any of the activities mentioned in points (a) and (b) of Article 16(2) complies with the relevant requirements. This guidance is also addressed to distributors and importers in respect to their quality management system to be certified by a notified body.

3 Quality Management System for distributors or importers

Without prejudice to general obligations that apply to all distributors (Article 14 MDR / IVDR) and importers (Article 13 MDR / IVDR), distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 of Article 16 of the MDR or IVDR are required to ensure that they have in place a quality management system. This quality management system includes procedures, which ensure that the translation of information supplied with the device is accurate and up-to-date. These procedures also ensure that those activities are performed by means and under conditions that preserve the original condition of the device. In addition, they ensure that the packaging of the repackaged device is not defective, of poor quality or untidy.

Furthermore, the procedures established under the quality management system should address elements related to contractual relationships in order to ensure compliance with certain provisions established by Article 16:

- Contracts with any economic operator the distributor or importer is purchasing the device from should ensure that the distributor or importer is informed in a timely manner about any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with the Regulation;
- In addition, the contract between the notified body and the distributor or importer should specify the possibility for the notified body to perform on-site audits at the premises of the distributor and importer or their subcontractors if needed, as specified in section 6 of this document.

Procedures being part of the quality management system should ensure that the activities according to Article 16 paragraph 2 points (a) and (b) performed by the distributor or the importer do not affect compliance of the device with the applicable requirements.

The quality management system should govern the structure, responsibilities, procedures, processes and management of resources required to implement the principles and actions necessary to achieve compliance with the provisions of Article 16(3) of the MDR / IVDR.

The quality management system is expected to cover and address at least the following:

- documentation of the management system, including responsibility of the management, and development of policies and procedures,

- resource management, including premises and equipment necessary to carry out activities referred to in points (a) and (b) of Article 16(2) as well as selection and control of suppliers and sub-contractors,
- policies for assignment of activities and responsibilities to personnel ensuring the availability of resources and information necessary to support the operation and monitoring of the activities mentioned,
- procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with the Regulation[5] (Article 16 paragraph 2 points (a) and (b)),
- management of corrective actions including procedures for handling non-conforming devices and market recalls due to the activities carried out under point (a) and (b) of Article 16(2), including, when necessary, field safety corrective actions and verification of their effectiveness,
- procedures to ensure traceability of the devices as well as labels, instructions for use and outer packaging indicating the changes made to the product,
- control of documents,
- control of records,
- supervision of the implementation and maintenance of the quality management system, including internal audits and management review.

The quality management system should be capable of supporting and demonstrating the consistent achievement of the requirements of Article 16(3) MDR / IVDR.

4 Certification scheme to be established by the notified body

Notified bodies performing certification activities according to Article 16(4) MDR / IVDR need to be designated for the type of devices that are subject to the activities mentioned in points (a) and (b) of paragraph 2 of Article 16 MDR / IVDR[6].

Notified bodies must be capable of carrying out all the tasks related to such certification activities and must have the necessary personnel that possess the competence needed[7].

In line with the organisational and general requirements set out in Annex VII MDR / IVDR, notified bodies must appropriately establish, document, implement and maintain:

- qualification criteria and procedures for selection and authorisation of all persons involved;
- documents and records concerning qualification of each member of personnel involved, including the maintenance of this qualification;

[5] It is manufacturer's responsibility to respond to safety issues and to bring the device into conformity. The distributor or importer should be informed about it.

[6] According to Article 16(4) MDR / IVDR this applies irrespective of the risk class of the devices, i.e. also for class I devices.

[7] This means that the notified body is expected to be designated for the corresponding MDA, MDN or IVR codes in Commission Implementing Regulation (EU) 2017/2185.

- processes and sufficiently detailed procedures for the conduct of certification according to Article 16(4) MDR / IVDR, comprising at least steps and aspects as:
  - (pre-)application and / or contractual activities, including quotations;
  - allocation of resources;
  - procedures sufficient to effectively plan and conduct both on-site and off-site assessment activities for auditing the distributor's or importer's management responsibilities and quality management system documentation [see section 3 of this document];
  - reporting procedures so that the conclusions of the assessment are clear and can represent objective evidence of such compliance to persons that are not themselves involved in the assessment, e.g. competent authorities;
  - final review and decision-making, including criteria for the issuance, suspension, restriction and withdrawal of certificates;
- procedures for dealing with changes and modifications, including possible extensions to the scope of certifications;
- surveillance activities ensuring that the distributor or importer consistently meets the requirements of Art 16(3), see section 6 of this document;
- procedures for re-certification, including maximum validity of certificates;
- procedures for complaints and appeals.

5 Content of certificates

Certificates according to Article 16(4) MDR / IVDR should be drawn up in one of the official languages of the Union and should be issued to only one distributor or importer. The name and address of the distributor or importer[8] has to be clearly specified and the scope of the certificates should unambiguously identify the types of devices covered. The MDA, MDN or IVR codes in Commission Implementing Regulation (EU) 2017/2185 have to be used to identify the types of devices. In case only subsections of such codes apply, limitations need to be identified using the wording(s) of the respective code. The scope should also mention the activities in points (a) and (b) of paragraph 2 of Article 16 MDR / IVDR. Where a certificate is supplemented, modified or re-issued, the new certificate should contain a reference to the preceding certificate and its date of issue with identification of the changes.

As a minimum, certificates need to contain the following information:

- name, address and identification number of the notified body;
- name and address of the distributor or importer;
- unique number identifying the certificate;
- date of issue;
- date of expiry;
- data needed for the unambiguous identification of the types of devices covered by the quality system using the wording of the code(s), if needed parts can be deleted or the scope may be

[8] The name and address of the importer referenced in the certificate should be the same as name and address registered in the electronic system referred to in Article 30 MDR and Article 27 IVDR.

further specified, e.g. MDA 0309 Active non-implantable ophthalmologic devices: applanation tonometers. EMDN (European Medical Device Nomenclature) codes may also be used for further identification of the types of devices;

- the activities in points (a) and (b) of paragraph 2 of Article 16 MDR / IVDR covered by the certificate, i.e.
  - provision, including translation, of the information supplied by the manufacturer in accordance with Section 23 of Annex I of MDR / IVDR, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;
  - changes to the outer packaging of a device already placed on the market, including a change of pack size.

  The activities should be linked to the abovementioned specific types of devices covered by the quality system;
- a statement that the quality management system of the distributor or importer that carried out any of the activities mentioned in points (a) and (b) of Art 16(2) complies with the requirements laid down in paragraph 3 of Article 16 MDR / IVDR;
- if applicable, reference to any previous certificate;
- information about the surveillance by the notified body;
- conditions for or limitations to the validity of the certificate;
- legally binding signature of the notified body in accordance with the applicable national law.

6 Surveillance and changes, including extensions to scope

Certificates issued according to Article 16(4) of MDR / IVDR should have a maximum validity of 5 years. The notified body should ensure that proper surveillance activities are performed, taking into account the following aspects.

6.1 Auditing

Initial certification of the distributor / importer's quality management system according to Article 16(4) should always include an on-site audit[9].

In order to verify the actual implementation as well as the proper functioning of a newly certified distributor / importer's quality management system, the notified body should perform annual surveillance audits. The need to perform on-site surveillance audits should be based on a risk assessment in respect to the auditee, its organisation and experience gained in the initial audit and follow-up activities.

Alternatively, provided that a shorter validity period of the certificate is set (maximum 3 years) the notified body may decide not to perform annual surveillance audits, unless it considers it necessary. After the first certification the notified body should perform one surveillance audit between 12 and max. 24 months in order to confirm the certified quality management system is actually in place and implemented.

[9] In duly justified cases when the notified body is unable to carry out the initial audit on-site, alternative measures can be applied, including remote audits. For these cases, it is anyhow expected the notified body to carry out an on-site audit as soon as possible and at the time of the first surveillance the latest.

At the end of each certification cycle, a re-certification audit should be conducted in order to renew the certificate. It is expected that notified bodies perform on-site re-certification audits[10]. Those re-certification audits should take place not earlier than 15 months before the end of validity of the certificate.

In case non-conformities are raised during the audits, additional audits may be conducted, either on-site or off-site, to verify the effectiveness of the implemented corrective actions. Additional audits may also need to be performed when the distributor or importer proposes (see section 6.2 below):

a) significant changes[11] to its processes covered by the certificate or

b) an extension of activities and types of devices to be covered by the certificate.

6.2 Assessment of change notifications[12]

Based on the contractual requirements the distributor or importer need to submit any plan for change that could affect the validity of the certificate according to Article 16(4) MDR / IVDR, especially those in respect to the activities and types of devices covered.

In case of plans concerning relabelling and / or repackaging of new types of devices not previously indicated on the Art 16(4) certificate, the distributer or importer should verify that the notified body that issued the certificate is designated also for the new type(s). If this is not the case, the distributor or importer should apply to a notified body bearing the required designation[13].

The notified body should assess such change notifications and, depending on the type of the proposed change, decide if there is the need to perform an audit, either on-site or off-site, prior to their approval. Changes that have a significant impact on the activities to be certified under Article 16(4) such as broadening the scope of certificate, including new types of devices not previously indicated on the Art 16(4) certificate, concerning the activity in Article 16 (2) b) or change of the site(s) (including subcontractors) where those activities are performed, should always require an on-site assessment[14]. In case of new activities or new types of devices, the certificate needs to be supplemented.

[10] Similarly to initial audits, also in case of re-certification audits, alternative measures can be applied, including remote audits when the notified body is unable to carry out the audit on-site.

[11] For the purpose of this document, significant changes are meant as changes having a significant impact on the activities to be certified under Article 16(4), as referred to in paragraph 6.2 of this document.

[12] For notification obligations of distributors and importers see Questions & Answers for distributors and importers.

[13] The distributor or importer can either ask for a voluntary change to a notified body designated for all types of relabelled / repackaged devices or have two (or more) separate notified bodies certifying the quality management system for different types of devices according to Article 16(4).

[14] Alternative measures can be applied in duly justified cases.