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Guidance on Article 15 of the medical device regulation (MDR) and *in vitro* diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)

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MDCG 2019-07 (June 2019) **MDCG 2019-07 Revision 1 changes (Dec 2023)**	
General	Document sections re-ordered to follow numbering of Article 15 MDR/IVDR paragraphs Reference to '*in vitro* diagnostic medical devices' added throughout document
Introduction	New section added Footnotes: 1, 2 (added)
Manufacturers (Article 15 (1))	Clarification on qualifications: new text added on '*course of study*', minor amendment to second bullet on '*qualification acquired outside the EU*..' Professional experience: new sentence followed by paragraph added starting from '*The professional experience should be substantive...*' Custom-made devices: new sub-section added PRRC location: deletion of first 5 words Footnotes: 3 (amended) 4, 5, 6 and 8 (added)
Micro and small manufacturers (Article 15 (2))	Meaning of "*permanently and continuously at their disposal*": addition regarding availability requirements provided starting with *'of the PRRC. This may clarify*…' before last sentence. Footnotes: 9, 10 (added)
Roles and responsibilities of the PRRC of a manufacturer (Article 15(3))	Two new sentences added to introductory paragraph starting with '*The PRRC has a key role in…'* Additions made regarding the following articles Art 15(3)(a),(c),(d) Final paragraph added Footnotes: 11,12 (added)
The PRRC 'shall suffer no disadvantage' (Article 15(5))	New section added
Authorised Representatives (Article 15(6))	Clarification on qualifications: new section added Custom-made devices: new section added Meaning of "*permanently and continuously at their disposal*": same addition regarding availability requirements as made regarding Art 15(2) PRRC location: addition to last sentence
Roles and responsibilities of the PRRC of an authorised representative	Title: reference to 'paragraph 3' removed Can one individual be the PRRC for a manufacturer and its authorised representative: addition made regarding large organisation added starting with '*even in the event of*…'.
Entities assuming the obligations of a manufacturer	New section added
Registration of the PRRC in Eudamed	New section added

Introduction

Article 15 of Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) introduces the new role of a person responsible for regulatory compliance (PRRC), and the obligation for a manufacturer and authorised representative to have such a person at their disposal. This new role is intended to ensure that the supervision and control of the manufacture of devices, and the post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organisation by a person responsible for regulatory compliance, who fulfils the minimum conditions of qualification for the role.

The appointment of a PRRC is applicable for manufacturers, whether established inside or outside the EU, placing devices on the Union Market[1] and authorised representatives of non-EU manufacturers. The term 'device' will be understood to include medical devices, accessories for medical devices, products listed in Annex XVI of the MDR, *in vitro* diagnostic medical devices, accessories for *in vitro* diagnostic medical devices and also, custom-made devices[2]. References to 'the Regulations' should be understood to cover both the MDR and IVDR.

This document provides guidance on the roles and obligations of the PRRC and is addressed to manufacturers, authorised representatives and PRRCs.

Manufacturers[3] (Article 15 paragraph 1)

"*Manufacturers shall have available **within their organisation** at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices/in vitro diagnostic medical devices[4]. The requisite expertise shall be demonstrated by either of the following qualifications:*

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices/in vitro diagnostic medical device.

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices/in vitro diagnostic medical device.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first

[1] The 'Union market' refers to the territories of the European Union Member States, and due to the European Economic Area (EEA) is extended to Norway, Lichtenstein and Iceland, and via the Customs Union Agreement to Turkey. For Turkey, please see also the 'Notice to stakeholders EU-Turkey Customs Union Agreement in the field of medical devices' on the Commission website.
[2] Please see MDCG 2021-3 'Questions and Answers on Custom-Made Devices & considerations on Adaptable medical devices and Patient-matched medical devices' for more information on obligations relating to custom-made devices.
[3] Enterprises which employ at least 50 persons and whose annual turnover and/or annual balance sheet total exceeds EUR 10 million (based on the "definition" of small enterprises Commission Recommendation 2003/361/EC of 6 May 2003, Article 2(2)).
[4] Note that PRRCs appointed under Art 15(1)(a) MDR for medical devices and Art 15(1)(a) IVDR *in-vitro* diagnostic medical devices respectively, should have relevant experience in that field.

subparagraph by having at least two years of professional experience within a relevant field of manufacturing."

Clarification on qualifications

It shall be noted that:
For the purpose of fulfilling the requirement laid down in point "a" of Article 15 (1):

- as an alternative to a university degree, the provision allows for a 'course of study' in the fields of '*law, medicine, pharmacy, engineering or another relevant scientific discipline*', the formal qualification of which needs to be '*recognised as equivalent by the concerned Member State*' to the formal qualification awarded on completion of a university degree.
- where a qualification is acquired outside the EU, including any university diplomas, or certificates or evidence of a formal qualification on completion of a 'course of study', it is sufficient to have been recognised by one EU Member State as equivalent to the corresponding national qualification (based on documentation presented by the manufacturer), this could for example be the Member State where the manufacturer or authorised representative is located.

Professional experience in regulatory affairs or in quality management systems relating to medical devices/in vitro diagnostic *medical devices* should be related to the EU requirements in the field. The professional experience should also be substantive, and recent, meaning the experience would enable the appointed person to effectively carry out the duties of a PRRC.

It is the responsibility of the manufacturer to gather sufficient evidence that the PRRC they appoint meets the qualifications and is capable of fulfilling the roles and obligations outlined in Article 15 of the Regulations. Examples of such evidence may include but is not limited to, the *Curriculum Vitae*, copies of all relevant certificates held, including evidence that the PRRC has in fact obtained the requisite professional experience[5]. It is recommended that such documents are recorded and maintained by the manufacturer as proof the appointed PRRC holds the requisite expertise to fulfil its responsibilities. Such documentation may also be requested by competent authorities in the course of market surveillance activities, for example, during an inspection carried out under Article 93(3)(b) MDR/Article 83(3)(b) IVDR.

Custom-made devices:

For manufacturers of custom-made devices, to fulfil the 'requisite expertise' required under Article 15(1) of the MDR, it is sufficient to appoint a person responsible for regulatory compliance that has at least two years of professional experience within a relevant field of manufacturing (including technology). This professional experience does therefore not need to be accompanied by evidence of a formal qualification as described in Article 15(1)(a) of the MDR in addition.

This professional experience should also cover regulatory and/or quality management system aspects and it is recommended that the experience be relevant to the class of custom-made device, particularly in case of implantable devices. In terms of demonstrating professional experience, providing for example evidence of two years of employment in a company that

[5] It is noted that for example, experience limited to administrative handling of documents and shadowing of regulatory affairs professionals, would not be considered sufficient.

manufactures custom-made devices without providing evidence of the skills acquired, is not sufficient.

Meaning of "*within their organisation*"

The person responsible for regulatory compliance (PRRC) appointed would need to be an employee of the organisation.

Organisations with more than one legal manufacturer

Organisations with more than one legal manufacturer under the parent company would need to ensure that each legal manufacturer has its own PRRC[6].

Can the PRRC be located outside the Union?

It is important that a close linkage of a permanent and continuous nature is established between the PRRC and the manufacturing activities. For this reason, for manufacturers located outside the Union, it must be assumed that the PRRC should also be located outside the Union[7]. On the other hand, for manufacturers located in the Union, it must be assumed that the PRRC should also be located in the Union.

Micro and small manufacturers[8] (Article 15 paragraph 2)

"*Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC* ***shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal***."

Meaning of "*permanently and continuously at their disposal*"

The micro or small enterprise may subcontract the responsibilities of a person responsible for regulatory compliance to a third party, so long as the qualification criteria are met and the manufacturer can demonstrate and document how they can meet their legal obligations. For example, the PRRC may be part of an external organisation, with which the manufacturer has established a contract laying down provisions so as to ensure the permanent and continuous availability of the PRRC. This may clarify how the availability requirements are intended to be met so the duties of the PRRC can be carried out effectively (e.g., that the PRRC should be available to perform its operational duties and react in a timely manner, whilst not necessarily implying 24-hour availability on a daily basis). The contract should mention the relevant person's qualifications allowing compliance with points a and b of Article 15 (1) of the Regulations.

[6] In the context of Article 15, the obligation for having available within the organisation at least one PRRC refers to the individual legal manufacturer.
[7] Given 'outside the Union' is a large geographical territory, the PRRC's location is recommended to be e.g., in physical and geographical proximity to the manufacturing activities.
[8] According to Commission Recommendation 2003/361/EC of 6 May 2003, article 2: Small enterprise (manufacturer): an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million; Micro enterprise (manufacturer): an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.

Can the PRRC be located outside the Union?

For micro or small enterprises located in the Union, it must be assumed that any person to be permanently and continuously at their disposal should be also located in the Union. For manufacturers located outside the Union, it must be assumed that the PRRC should also be located outside the Union[9].

Roles and responsibilities of the person responsible for regulatory compliance of a manufacturer (Article 15 paragraph 3)

For the purpose of this guidance, the roles and responsibilities of a PRRC have been cross-referred to the roles and responsibilities of a manufacturer, as stated in Article 10 of the Regulations, however this guidance does not further interpret the roles and responsibilities of a PRRC. The PRRC has a key role in the manufacturer's organisation in verifying the manufacturer's compliance with the Regulations. As such, the manufacturer should involve the PRRC in the processes it deems relevant and enable the PRRC to receive all necessary information (e.g., any identified non-conformities), for the PRRC to perform its tasks effectively. Regardless of how the term 'PRRC' is translated in different official Member States languages, it is noted that the PRRC remains responsible for the activities listed in Article 15.3 of the Regulations.

"*The person responsible for regulatory compliance shall at least be responsible for ensuring that:*

(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;"

Manufacturers "*of devices, other than devices for investigational devices/devices for performance study, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device*" (Article 10(9) of the MDR and Article 10(8) of the IVDR).

The demonstration of conformity of devices with the Regulations remains the responsibility of the manufacturer. The PRRC within their role however is expected to ensure that devices for release by the manufacturer have followed procedures established in its quality management system before being placed on the market. The PRRC may carry out this activity for example, by means of auditing or sampling the following (non-exhaustive examples):

- the required documentation exists and may assess the relevance and consistency of these documents (i.e., the presence of a document is not sufficient to conclude that it complies with the regulatory requirements);
- the technical documentation contains all documents quoted in the checklist of general safety and performance requirements;

[9] Given 'outside the Union' is a large geographical territory, the PRRC's location is recommended to be e.g., in physical and geographical proximity to the manufacturing activities.

- the relevant test reports are valid and according to the applicable versions of the standards used; when there are product changes[10], the technical documentation has been updated and contains the documents reflecting the change;
- all verifications, validations and other tests provided for in the QMS have been carried out before devices are released.

"*(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;*"

Manufacturers "o*f devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices" (Article 10(4) of the MDR and IVDR) and "shall draw up an EU declaration of conformity" (Article 10(6) of the MDR and Article 10(5) of the IVDR)*.

"*(c) the post-market surveillance obligations are complied with in accordance with Article 10(10) of the MDR (Article 10(9) of the IVDR);*"

Manufacturers "*of devices shall implement and keep up to date the post-market surveillance system" (Article 10(10) of the MDR and Article 10(9) of the IVDR)*.

To ensure this, the PRRC may assess the relevance and functioning of the post-market surveillance system and whether it enables appropriate data collection in order to support the continuous maintenance of device safety and performance or improvement thereof.

"*(d) the reporting obligations referred to in Articles 87 to 91 of the MDR (Article 82 and 86 of the IVDR) are fulfilled;*"

Manufacturers "*shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88 of the MDR (Articles 82 and 83 of the IVDR)" (Article 10(13) of the MDR and Article 10(12) of the IVDR)*.

The PRRC should also ensure that the vigilance reporting obligations are fulfilled, including the systematic reporting of serious incidents, field safety corrective actions and trend reporting[11].

"*(e) in the case of investigational devices and/or devices for performance studies intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects, the statement referred to in Section 4.1 of Chapter II of Annex XV of the MDR (Section 4.1 of Chapter II of Annex XIV of the IVDR) is issued.*"

Manufacturers shall ensure that "*a signed statement by the natural or legal person responsible for the manufacture of the investigational device/device for performance study, that the device in question conforms to the general safety and performance requirements laid down in Annex I apart from the aspects covered by the clinical investigation /performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.*"

[10] For devices requiring the intervention of a notified body, it is noted that manufacturers have information obligations towards their notified body regarding changes and modifications (Section 4.9. of Annex VII of the Regulations), which should be fulfilled before implementation of a change or modification.
[11] Please see MDCG 2023-3 'Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices' for more information on vigilance reporting.

Finally, given the importance of the role of the PRRC and its involvement in different organisational procedures, the PRRC should inform the manufacturer in the case where it is unable to meet its obligations under Article 15 of the Regulations.

The person responsible for regulatory compliance '*shall suffer no disadvantage*' (Article 15 paragraph 5)

"*The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation*".

The PRRC should not suffer any disadvantage and this may include, for example dismissal or, being penalised for performing their tasks dutifully.

Authorised representatives (Article 15, paragraph 6)

"*Authorised representatives shall have **permanently and continuously at their disposal** at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:*

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices."

<u>Clarification on qualifications</u>

For the purpose of fulfilling the requirement laid down in point "a" or point ''b'' of Article 15 (6), the clarifications provided in the above section on 'Manufacturers, (paragraph 1)' to demonstrate the 'requisite expertise' of the PRRC pertaining to qualifications and 'professional expertise', also apply.

<u>Custom-made devices</u>

Authorised representatives of non-EU manufacturers of custom-made devices should also have a PRRC permanently and continuously at their disposal. The requisite expertise of this PRRC may be demonstrated under the same conditions outlined in points (a) or (b) of Article 15(6) of the Regulations.

<u>Meaning of "*permanently and continuously at their disposal*"</u>

The authorised representative may subcontract the responsibilities of a person responsible for regulatory compliance to a third party, so long as the qualification criteria are met and the authorised representative can demonstrate and document how they can meet their legal

obligations. For example, the PRRC may be part of an external organisation with which the authorised representative has established a contract laying down provisions so as to ensure the permanent and continuous availability of the of the PRRC. This may clarify how the availability requirements are intended to be met so the duties of the PRRC can be carried out effectively (e.g. that the PRRC should be available to perform its operational duties and react in a timely manner, whilst not necessarily implying 24-hour availability on a daily basis.) The contract should mention the relevant person's qualifications allowing compliance with points a and b of Article 15 (6) of the Regulations.

Can the PRRC be located outside the Union market?

Taking into account that the Authorised Representative is located in the Union market, it must be assumed that any person to be permanently and continuously at its disposal should be also located in the Union market in order to effectively fulfil their responsibilities.

Roles and responsibilities of the person responsible for regulatory compliance of an authorised representative

The PRRC of an authorised representative should be responsible for ensuring that the tasks of an authorised representative as specified in the given mandate, in accordance with Article 11(3) of the Regulations, are fulfilled.

Can one individual be the PRRC for a manufacturer and its authorised representative?

The person responsible for regulatory compliance for an authorised representative and for an 'outside EU' manufacturer cannot be the same person, even in the event of the 'outside EU' manufacturer and its authorised representative are part of the same large organisation. There is a clear desire within the Regulations for the authorised representative to add an additional level of scrutiny and ensure that the supervision and control of the manufacture of devices, and the relevant post-market surveillance and vigilance activities are adequately performed. If the two roles were conducted by the same person, the additional level of scrutiny would be undermined.

For the same reason, the PRRC of a micro or small enterprise and the PRRC of the authorised representative of that same enterprise shall not belong to the same external organisation.

Entities assuming the obligations of a manufacturer

Article 16(1) of the Regulations outlines cases where the obligations of manufacturers also apply to importers, distributors or other natural or legal persons. In these cases where the importer, distributor or other natural or legal persons assumes the obligations of the manufacturer, Article 15 of the Regulations to appoint a PRRC also applies to the party assuming the responsibilities of the manufacturer. Similarly, in cases where it is specified in the Regulations that a natural or legal person when performing a defined activity, assumes the role of a manufacturer (e.g. Article 17 MDR on 'single-use devices and their reprocessing' and Article 22(4) on 'systems and procedure packs'), the Article 15 obligation to appoint a PRRC also applies to those entities.

Registration of the PRRC in Eudamed

To fulfil their registration obligations under Article 31(1) MDR and Article 28(1) IVDR, manufacturers and authorised representatives should register in Eudamed the information in section 1 of part A of Annex VI of the Regulations, including the name address and contact details of the PRRC. If any changes occur in this information (for example, contact details change or the contract with the PRRC is terminated and a new PRRC is appointed), manufacturers and authorised representatives should update this information within one week, in line with Article 31(4) MDR/Article 28(4) IVDR.