TEAM-PRRC

The European non-profit organization of Persons Responsible for Regulatory Compliance

Position paper No4 on the responsibilities of a PRRC within an Authorised Representative

For Persons Responsible for Regulatory Compliance according to article 15 of MDR (EU) 2017/745 and IVDR (EU) 2017/746

The information summarized in this document reflects the current understanding of the EU Requirements and may be subject to a regular change over the upcoming years.

Version 1 : July 2022

Written by : The Board of TEAM-PRRC

Contents

ABBREVIATIONS **3**

1. INTRODUCTION **4**

2. REGULATORY REQUIREMENTS AND GUIDANCE **4**

2.1. THE REGULATIONS 4

2.2. MDCG GUIDANCE 5

3. THE QUALIFICATIONS OF THE PRRC **6**

3.1. ARTICLE 15 (6) 6

3.2. THE USE OF AN OUTSOURCED PRRC 7

4. THE RESPONSIBILITIES OF THE PRRC **7**

5. THE LIABILITY OF THE PRRC **8**

6. LEGACY DEVICES **10**

7. PRACTICAL IMPLICATIONS OF THE AR-PRRC **10**

7.1. IMPACT OF THE AR-PRRC ROLE ON THE ACTIVITIES OF AN AR 10

8. CONCLUSION **12**

9. PRESENTATION OF THE ASSOCIATION **13**

9.1. THE OBJECTIVES OF TEAM-PRRC 13

9.2. RESOURCES 13

9.3. WHO MAY JOIN THE ASSOCIATION? 14

9.4. BENEFITS OF MEMBERSHIP 14

Abbreviations

AR: Authorised Representative

CA: Competent Authority

EU: European Union.

FSCA: Field Safety Corrective Action

IVDR: *In Vitro* Diagnostic Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices.

MDR: Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

PRRC: Person Responsible for Regulatory Compliance.

AR-PRRC: PRRC at an Authorised Representative

QMS: Quality Management System

UDI: Unique Device Identifier.

1. Introduction

This position paper aims to:

- Understand the intent behind the role of AR-PRRC
- Describe the roles and responsibilities of the AR-PRRC
- Define the place of an AR-PRRC in the QMS of the various organizations
- Describe potential methods to fulfill the legal obligations described in the MDR and IVDR
- Acknowledge the liabilities of the AR-PRRC

This PRRC shall have a specific profile with minimum qualifications required by the regulations and described in Article 15 of the MDR and IVDR.

The role of PRRC is a new role appearing for the first time in both the medical device and in-vitro diagnostic regulations. This role is known from other regulations where a similar position is described:

- the pharmaceutical industry with the Qualified Person
- the cosmetics industry with the Responsible Person
- General Data Protection Regulation with the Data Protection Officer

2. Regulatory requirements and guidance

2.1. The Regulations

The AR-PRRC requirements come from:

- **Recital 35 in MDR (34 in IVDR)**

"Considering the role of authorised representatives, the minimum requirements they should meet should be clearly defined, including the requirements of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's person responsible for regulatory compliance."

- **Article 15 (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."

Article 15 requires that all Authorized Representatives (AR's) shall have at least one PRRC at their disposal.

- **Annex VI, part A of the MDR**

The MDR requires the AR-PRRC to be registered in EUDAMED when it is functional, and to submit the following information:

- Section 1.4 includes the need to register - "name, address and contact details of the person or persons responsible for regulatory compliance referred to in Article 15".

The information registered has to be complete, accurate and up-to-date. Registration in EUDAMED of the PRRC should take place as part of the AR entering their data.

TEAM-PRRC Position:

As a consequence of the requirements in Annex VI, Section 1.4, the name and contact details of the PRRC will also be visible on the public site of EUDAMED. TEAM-PRRC is of the opinion that making this name public without explicit permission of the individuals involved does not serve any legitimate purpose and these details should be made available only for the authorities.

2.2. MDCG guidance

The Medical Devices Coordination Group (MDCG) has published MDCG 2019-7 which is their guidance on Article 15 of the MDR & IVDR regarding a PRRC.

This guidance gives interpretation on the meaning of certain phrases of the article 15 but still leaves some key questions about PRRC responsibility unanswered. In particular it does not say anything about the responsibilities of the AR PRRC.

To summarize, this guidance states the following about the role of the AR-PRRC:

- EU Member States must recognise non EU qualifications.
- An outsourced PRRC can be considered "permanently and continuously available" if that is laid down in a contract. The AR-PRRC must be located in the EU because there has to be a "close linkage of a permanent and continuous nature" between the AR and PRRC, while the AR must be based by definition in the EU.
- The AR-PRRC cannot also work as PRRC for the manufacturer
- A PRRC is required whatever the class of risk of medical devices

TEAM-PRRC Position:

In addition, TEAM-PRRC is of the opinion that a PRRC must have direct access to upper management and provide them with their opinion either on request or unsolicited. Senior management should be made aware of a potential compliance breach as early as possible.

Case where the AR is a subsidiary of the manufacturer:

If the AR is a subsidiary of a non-EU manufacturer, this legal manufacturer must have their own PRRC outside the EU, who is responsible for their manufacturer's requirements. The AR must have their own separate AR-PRRC, who is responsible for the requirements specific for the AR. Each may or may not outsource this role, but in that case, these should also be different persons.

Case of an importer or distributor acting as the AR ('importer AR'): if an importer or distributor acts as the AR of a non-EU manufacturer they must appoint an AR-PRRC, although an importer or distributor is not required to appoint a PRRC[1]. By taking up the role of the AR they must also accept the specific tasks and responsibilities that come with that role, including appointing an AR-PRRC. The AR-PRRC is not responsible for compliance exclusively related to the role of that particular economic operator.

Case of an independent organization acting as the AR ('independent AR'): if a (legal) person acts as an AR for multiple manufacturers they must appoint at least one AR-PRRC. That AR-PRRC can oversee multiple companies, they do not have to appoint a different PRRC for each manufacturer.

3. The qualifications of the PRRC

3.1. Article 15 (6)

The requisite expertise for an AR-PRRC 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 recognized 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."

The qualifications required are the same as for a PRRC within a manufacturer, except that there is no mention of custom-made devices (article 15.1).

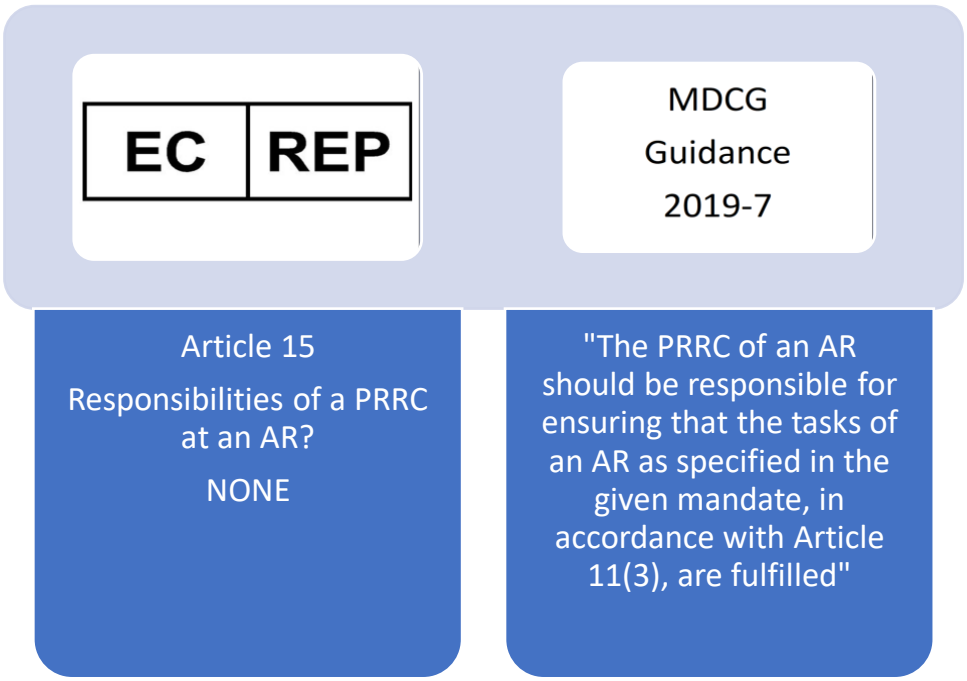
[1] Unless they are performing activities which are subject to the requirements of article 16 (MDR / IVDR)

3.2. The use of an outsourced PRRC

In the case of ARs, an external PRRC is permitted regardless their size and shall be continuously and permanently at the disposal of the AR.

Further information on contracts and location of the PRRC is discussed in the TEAM-PRRC Position Paper No.2.

4. The Responsibilities of the PRRC



The responsibilities of the manufacturer's PRRC are clearly spelled out in Article 15(3). However, some of these are not relevant for the AR-PRRC. In fact, there are no explicit responsibilities for the AR-PRRC specified in Article 15. The MDCG Guidance document 2019-07 states that the AR-PRRC should ensure that the tasks of an AR as specified in the given mandate are fulfilled.

When we look at Article 11(3), it specifies the minimum items that should be required within the mandate between the manufacturer and the AR.

Article 11(4), however, is clear that the manufacturer cannot delegate compliance, risk management, clinical evaluation, drawing up of technical documentation and the declaration of conformity, UDI assignment, setting up and maintaining of a QMS, supplying the user information in the appropriate language(s) and performing field safety corrective actions to the AR, although the AR may also act as a

consulting organization that provides the manufacturer with advice that the manufacturer may, or may not, follow[2].

TEAM-PRRC Position:

In the light of recitals 34 and 35 of MDR (33 & 34 of IVDR) it would seem that indeed there is intended to be a difference between the role of a Manufacturer's PRRC and an AR's PRRC.

The Manufacturer's PRRC is required to "ensure that the supervision and control of the manufacture of devices… are carried out **within the manufacturer's organization**". (Recital 34)

However, the AR '*plays a pivotal role in ensuring the compliance of devices produced by manufacturers'* and for this reason the AR is given joint and several liability with the manufacturer, and yet the AR-PRRC is not able to check the device conformity before its release.

As some of the manufacturer's obligations, as listed in article 11.4 of the Regulation, are not transferable to the AR, the AR-PRRC can only act within the activities of the AR. The AR is explicitly not responsible for the compliance of the devices and therefore the AR-PRRC can also not be held liable for that too. Clearly, the AR-PRRC must ensure the AR is acting in accordance with its requirements.

Furthermore article 11(3)(h) requires the AR to '*terminate the mandate if the manufacturer acts contrary to its obligations*' under the MDR. This may be simple for an independent AR who is representing several companies because they can probably compensate the loss of revenue caused by terminating that client[3]. However, for AR's that are a subsidiary of the manufacturer termination will put an end to their business. In these cases, TEAM-PRRC suggests the mandate should also include the requirement that the AR-PRRC should inform the manufacturer PRRC of any non-compliance they observe. In that way the non-compliance can be assumed to have been brought to the attention of the manufacturer so that the AR-PRRC can be seen to have discharged their duties under article 15. The requirement to terminate the mandate will remain in place, but it is likely the manufacturer takes appropriate action before termination has to become a reality. The AR-PRRC should also ensure that in case of termination of the mandate of a manufacturer that acts contrary to its obligation the relevant competent authority and, if relevant, the notified body, are immediately informed.

5. The Liability of the PRRC

This topic would benefit from further clarification. The penalties for PRRCs not properly fulfilling their duties depend on the national law of each Member State.

[2] An organisation acting as a consultant is not required to appoint a PRRC.

[3] In case of a suspected non-compliance the independent AR will probably contact the manufacturer and request them to correct this issue. Persisting non-compliance may result in termination of the mandate. The AR-PRRC should be closely involved in this process.

For the AR-PRRC who has the 'responsibility to ensure', liability is not in the MDR other than the manufacturer PRRC is to suffer no disadvantage. This is taken to mean that the individual should not be excluded from rewards, bonuses or promotions if mandates of non-EU manufacturers are rejected or nonconformities are raised within the organization of the AR regarding the compliance of the service provided by the AR. The Manufacturer and the ARs are liable for defective products (as legal entities). Where a PRRC is employed by the organization, the role is no different to that of any other staff with regulatory responsibilities and the regulations do not state that the PRRC holds any liability.

In the case of an external PRRC, the Manufacturer and the AR may assign some contractual liability to the company offering that external PRRC service. It is unlikely that any PRRC can be held personally liable for defective products but a Manufacturer or AR may be prosecuted by a Member State and these, in turn, could try to transfer liability onto the PRRC Company or the PRRC.

- *The PRRC shall suffer no disadvantage within the manufacturer's organization in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organization*." (Article 15.5) This assumes that PRRC employees are protected under EU employment law, the AR should contractually extend this to the AR-PRRC.
- Recital 31: the manufacturer is liable for the products or the damaged caused by their products. There is no mention of "insurance": the manufacturer just has to have sufficient financial coverage. Therefore, there is not a requirement for a PRRC to have insurance. We can suggest that the management of the company assess the risk of this situation to determine the financial coverage that is needed.
- Recital 35 – the AR also shares legal liability for defective devices.
- Both the manufacturer (Art 10.16) and the AR (Art. 11.5) are legal entities – they are liable and not the PRRC.

The MDR leaves it to the Member States to determine the penalties applicable to infringements of its provisions. TEAM PRRC regrets this information is not shared on a single location.

TEAM-PRRC Position:

TEAM-PRRC is of the opinion that a company may be found in non-conformity with Article 15. However, Article 15 is written in such a way that the PRRC cannot be in non-conformity of this article. When the PRRC has to start performing their tasks to ensure these various activities are completed correctly, they need to know how they might be involved in the process. There are, as illustrated above, several ways in which the PRRC can "ensure", "have responsibility", "watch" or "have oversight" but however these activities are interpreted, objective evidence should be generated to demonstrate what they carried out. The PRRC must establish that all relevant procedures are drawn up, implemented and maintained. This can be done by verifying the presence of a valid certificate for the quality management

system. If that is not available the audit can be done by the PRRC. The PRRC must also verify all relevant forms and templates. Execution of procedures can be verified on sampling basis, as applicable.

TEAM-PRRC further recommends the AR-PRRC to have in their appointment letter a statement that their organization will apply Article 15(5) as if this is also covering the AR-PRRC.

6. Legacy Devices

MDCG guidance document 2021-25 on legacy devices states that a PRRC is not required for legacy devices. However, TEAM-PRRC believes that the scope of the AR-PRRC covers more than only the certification of the devices. Article 120(3) addresses 'a device' and allows this to be placed on the market certified by valid AIMDD or MDD certificates, as long as it complies with either of those directives and complies with specific requirements of the MDR. Article 120(3) does not allow economic operators to follow the Directives instead of the MDR.

TEAM-PRRC Position:

TEAM-PRRC is of the opinion that this may result in situations where the AR-PRRC get into a conflict of interest, because the protection of Article 15(5) does not apply in the case where a PRRC speaks out about a non-conformity involving a legacy device. Although the AR-PRRC is not protected by Article 15(5), TEAM-PRRC recommends to make that article also applicable for the AR-PRRC (see above). Therefore, TEAM PRRC also recommends that the AR and their PRRC agree that, in relation to the role of the PRRC, legacy devices still in transition are treated the same as devices that are certified according to the MDR or IVDR as applicable.

There is no transition period to appoint an AR-PRRC, so the AR-PRRC needs to be assigned at the latest by the date the first device is placed on the market under the mandates, regardless of whether they represent devices CE marked under the Regulations or under the Directives.

7. Practical implications of the AR-PRRC

7.1. Impact of the AR-PRRC role on the activities of an AR

Although ARs are not specifically required to have a quality management system, they may need to consider documenting the following when appointing an AR-PRRC.

1) **Recruitment:** Document a letter of appointment/ contract / job description. Plan for absence cover or if the PRRC leaves the company.

2) **Approvals:** Consider where the PRRC needs to be in the approval process for accepting a mandate with the manufacturer.
3) **Management responsibilities:** Allow the PRRC to have the organizational freedom to exercise their obligations and ensure that all senior management are aware of the PRRC's responsibilities. Determine how responsibilities will be divided if more than one PRRC is appointed.
4) **Management of data:** PRRC details have to be registered in EUDAMED when an AR first registers for their Single Registration Number.
5) **PRRC information:** any report, opinion or other relevant communication of the PRRC must be stored in such a way it can be accessed for later review.

❖ The AR-PRRC is not required to perform these activities themselves but must at least liaise with other departments or roles such as:

- **Sales**: for ensuring the onboarding of a new non-EU manufacturer, adding a new generic device group to an existing mandate, or adding a new device to an existing generic device group on the mandate, follows the correct procedures
- **Regulatory Affairs**: for verification of correct drawing up of the mandate(s), for registration of economic operators and devices, for verification and availability of declarations of conformity and technical documentation, for verification of vigilance reporting and for communication with the authorities and/or the manufacturer
- **Management:** for termination of mandates if a manufacturer acts contrary to its obligations under the Regulation

❖ Who will the AR-PRRC report to?

- **Senior management if applicable:** the PRRC must have disciplinary authority to empower them to make "ensuring" possible. Regarding the policies and procedures provided, the PRRC must have the support of senior management in relation to its obligations under MDR.
- **The PRRC of the non-EU manufacturer:** especially in the case of an AR that is a subsidiary of the manufacturer, the AR-PRRC may feel they have to inform the PRRC of the non-EU manufacturer about a potential trigger for a mandate termination.

Certain records also need to be visible to the PRRC. Below is a list of potential methods available to a PRRC to be used in fulfilling their responsibilities:

1) **Mandate related documentation:** approval of text of (template) mandate, approval of procedure to verify technical documentation, audit of results of verification

2) **Availability of technical file and declaration of conformity** and other relevant documents listed in annex IX - chapter III, at the disposal of the competent authorities*: audit of location and verification
3) **PMS obligations met:** audit of evidence of communication with manufacturer, relevant authorities and other economic operators.
4) **Vigilance obligations met:** approval of procedure to cooperate with the authorities on preventive or corrective actions and audit of possible evidence of such actions

An approval is a complete review of every record or document, while auditing is a sampling process. The choice of method used might depend on the number of types of devices, the production volumes to be released and the complexity of each device. Whatever methods are chosen, it is important that the PRRC creates documented evidence of how they have fulfilled their responsibilities.

* where the manufacturer is based outside the EU, its AR shall keep all technical documentation and other relevant documents listed in annex IX - chapter III, at the disposal of the competent authorities:

- *The EU Declaration of Conformity*
- *The documentation referred to in the fifth indent of Section 2.1 (which is the documentation on the manufacturer's quality management system) and in particular the data and records arising from the procedures referred to in point (c) of the second paragraph of Section 2.2 (the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques),*
- *Information on the changes referred to in Section 2.4 (The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered.),*
- *The documentation referred to in Section 4.2 (the technical documentation as referred to in Annexes II and III), and*

The decisions and reports from the notified body as referred to in this Annex.

8. Conclusion

Independent or manufacturer affiliated ARs are required to appoint an AR-PRRC, which must be a different person than the PRRC of the manufacturer. Where the PRRC is responsible for the regulatory compliance of the AR, the AR is responsible for their compliance with the mandate held between them and the manufacturer.

Whilst the responsibilities of the AR-PRRC can be compared to those of the Manufacturer-PRRC, they are not the same. Arguably, the AR-PRRC has more to do in that the list of documentation that they are

potentially required to check is longer. Additionally, this could potentially vary greatly depending on the extent of the different mandates held for those ARs with multiple clients. Consequently, the AR-PRRC must have ways of keeping track of the requirements of different mandates with different types of manufacturers of different products.

9. Presentation of the Association

TEAM-PRRC has been established as a non-profit organization dedicated to the profession of « Person Responsible for Regulatory Compliance » (PRRC) according to the article 15 of the MDR and IVDR:

- to help regulatory affairs experts in the healthcare system understanding their obligations as PRRC,
- to support PRRCs with additional guidance and best practice documents ensuring harmonised implementation of the requirements in the EU, and
- to represent the interest of PRRCs in front of the European regulators and stakeholders including the EU Commission, EU Ministries, Competent Authorities, Medical Associations, Industry Associations and Notified Bodies.

9.1. The objectives of TEAM-PRRC

TEAM-PRRC is established with the following objectives:

- Establish a platform for all PRRCs following the requirements of the regulations.
- Ensure more clarities regarding the qualification requirements and obligations of the PRRCs.
- Develop and implement educational system specifications towards recognized qualification criteria of PRRC.
- Establish, maintain and develop continuous knowledge sharing across all PRRCs.
- Represent the need of all PRRCs via one single non-profit organization towards more harmonization.

9.2. Resources

The non-profit organization is led by key subject matter experts who volunteered to support the implementation of the regulations (MDR and IVDR) by dedicating part of their time for this activity.

The Board includes:

- President – Elem Ayne

- Vice President – Anne Jury
- Vice President – Bassil Akra
- Secretary – Jean-Louis Divoux
- Treasurer – Vacant position
- Member of the Board – Ronald BOUMANS

The Board is supported by a group of experts advisors and contributors.

9.3. Who may join the association?

There are three ways to join the association:

1) Active members: All persons who comply with the requisite expertise listed in the article 15 §1 of the MDR and the IVDR. Each active member has declared that they are committed to following the Team-PRRC Code of Ethics and are the only type of member with voting rights.
2) Supporting members: Persons who do not meet the above criteria but have an interest in the role of PRRC and can contribute towards supporting the organization in the clarification of specific quality or regulatory questions.
3) Sponsorship: All organizations (companies) which want to support our association

9.4. Benefits of Membership

The members can benefit from:

- Legal assistance when drafting and issuing a contract
- Access to the training organizations fulfilling the minimum criteria mentioned in the regulations MDR and IVDR
- Access to helpful procedures and templates including but not limited to Letter of appointment, job description and etc.
- Continuous update about the legal requirements and their interpretations
- Information on relevant conferences and webinars
- Access to on-demand mediation in case of internal or external conflicts

--oOo--