TEAM-PRRC

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

Position paper No3 on the responsibilities of a PRRC within a manufacturer – the practical application of Article 15§3

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

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

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Written by : The Board of TEAM-PRRC

Contents

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

MF-PRRC: PRRC at a Manufacturer

AR-PRRC: PRRC at an Authorised Representative

PSUR: Periodic Safety Update Report

QMS: Quality Management System

UDI: Unique Device Identifier

1. Introduction

This position paper aims to:

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

The 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 PRRC requirements come from:

- **Recital 34 in MDR (33 in IVDR)**

"It should be ensured that 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 minimum conditions of qualification."

- **Article 15 (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."

Article 15 requires that manufacturers shall have at least one PRRC regardless of whether they reside inside or outside of EU.

However, in certain cases, when importers and distributors or any other natural or legal person are performing activities like manufacturers, they will also need a PRRC (articles 16 and 22 of the MDR).

This is the case if this person:

- makes available on the market a device under its name, registered trade name or registered trade mark (except in cases where the manufacturer enters into an agreement whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers by the regulation),
- changes the intended purpose of a device already placed on the market or put into service,
- modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.
- Case for pharmaceutical manufacturers:
- Regarding pharmaceutical manufacturers that have non-CE-marked devices or device parts that will be used as drug-device combination products, such as syringes to be prefilled, do not need to have a PRRC if the products are not placed on the market under MDR or IVDR.

2.2. Annex VI, part A of the MDR

The MDR requires the PRRC to be registered in EUDAMED, and to submit the following information:

- Section 1 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 of the PRRC in EUDAMED should take place as part of the manufacturer entering their data.

2.3. 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.

2.4. Case where several legal manufacturers belong to the same Group:

If there are several legal manufacturers belonging to the same Group, these legal manufacturers must have their own PRRC "within their organisation". The MDCG guidance specifies that "within their

organisation" means that the PRRC must be an employee of this organisation. But we have to distinguish two cases:

2.4.1. If none of the legal manufacturers within the Group meet the criteria of a small enterprise or microenterprise (less than 50 persons and annual turnover and/or annual balance less than 10 million euros), the PRRC must be employed by each legal manufacturer. It could be the same person, provided that the PRRC is employed simultaneously by all legal manufacturers concerned.

2.4.2. If some of the legal manufacturers within the Group meet the criteria of small enterprise or microenterprise, these legal manufacturers may subcontract the responsibilities of the PRRC to a third party, which might be another legal manufacturer within the Group. In such a case, all legal manufacturers of the Group which meet the criteria of small or microenterprise might have the same external PRRC but this person shall be permanently and continuously at the disposal of all these manufacturers.

3. The qualifications of the PRRC

3.1. Article 15 (1)

“The requisite expertise shall be demonstrated by either of the following qualifications:

- 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;
- four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.”

The qualifications required are the same for a PRRC within an AR, except that there is no mention of custom made devices (article 15.6).

Further information on the practical application of the qualification requirements is discussed in the TEAM-PRRC Position Paper No.1.

3.2. The use of an outsourced PRRC

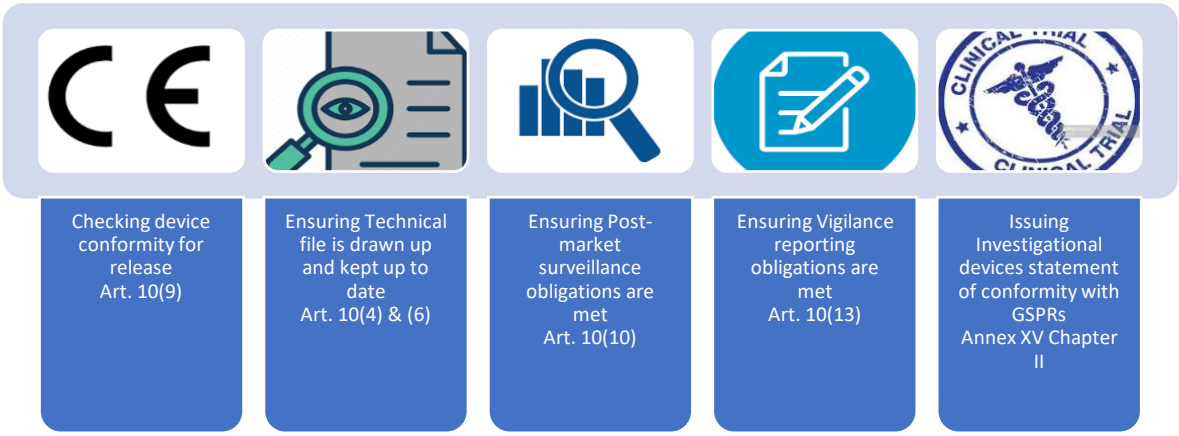
Article 15 (2)

In the case of micro and small enterprises, an external PRRC is permitted and shall be continuously and permanently at the disposal of the manufacturer.

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

4.1. Overview



The responsibilities of the PRRC are spelled out in Article 15(3) and parallels for the manufacturers responsibilities can mostly be found in Article 10 General obligations of the manufacturer. However, there is no further detail or guidance on how these responsibilities might be actioned, for example, "ensuring that technical documentation is drawn up".

Regarding the release of investigational devices, it would appear that the regulations do not require the PRRC to be directly involved in the release of investigational devices, only that they must meet the requirement in Art. 15.3 e) to ensure that the signed statement in Annex XV 4.1 is issued).

TEAM-PRRC Position:

A realistic scenario could be that a start-up company is not yet placing devices on the market and therefore is not yet acting as a manufacturer. As a consequence they do not have a PRRC. TEAM-PRRC is of the opinion that in a situation where the employer or contract-giver does not yet qualify as an economic operator, the requirement in Article 15.3(e) is not applicable.

4.2. Designating the PRRC role

As the manufacturer can appoint more than one PRRC, so the responsibilities can be shared over two or more people who are jointly responsible. If this approach is used, there should be documentary evidence of who is delegated and for what specific responsibilities.
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 organisation**". (Recital 34)

This might be a good intention but TEAM-PRRC are concerned that this internal market surveillance will lead to a situation where PRRCs are regarded with caution by their employers leading to less freedom to do their jobs effectively.
Finally, there is no transition period to appoint a PRRC within a Maufacturer, so this PRRC needs to be assigned at the latest by the date the first device is placed on the market, regardless of whether they represent devices CE marked under the Regulations or under the Directives.

TEAM-PRRC Position:
MDCG guidance document 2021-25 on legacy devices states that a PRRC is not required for legacy devices. However, TEAM-PRRC is of the opinion that the scope of the MF-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 is of the opinion that this may result in situations where the PRRC finds themselves in a conflict of interest, in that the protection of Article 15(5) would not apply in case a PRRC speaks out about a non-conformity involving a legacy device. The protection that the PRRC shall suffer no disadvantage would only work if article 15.5 is considered applicable. Therefore, TEAM PRRC recommends that the manufacturer and the PRRC agree that in relation to the role of the PRRC, legacy devices are treated the same as devices that are certified according to the MDR or IVDR as applicable.

4.3. Impact of the PRRC role on the QMS

The QMS may need some revision upon the appointment of a PRRC.

- **Recruitment:** Document a letter of appointment/ contract / job description. Plan for absence cover or if the PRRC leaves the company.
- **Approvals:** Consider where the PRRC needs to be in the approval process for procedures involved in the activities described in Article 15.3.
- **Management responsibilities:** Ensure visibility and assign authority of the PRRC throughout the organisation. 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.

Note: EN ISO 13485 5.5.2 – The Management Representative is not the same as the PRRC. However, it is allowed that the PRRC also acts as the Management Representative.

Management of data: The PRRC's contact details have to be registered in EUDAMED when a manufacturer first registers for their Single Registration Number.

TEAM-PRRC Position:

When appointing the PRRC, the company must ensure the requirements of the General Data Protection Regulation are met. This means ensuring there is written permission from the PRRC to share their contact information publicly. Alternatively, while taking on the role of PRRC, the candidate should check it the letter of appointment includes a formal request for permission to share contact details.

PRRC reports / correspondence / records: Any report, opinion or other relevant communication of the PRRC must be documented and stored as part of the QMS records in such a way that it can be accessed for later review.

QMS Documentation: Not only does the PRRC have to oversee the tasks outlined in Article 15.3 but just by existing, they need to be acknowledged within the QMS, perhaps in Roles and Responsibilities or in the Organisation Chart. Also useful is a contingency plan within Human Resources department in case the PRRC is absent for a long period or leaves the company. Change control procedures will also perhaps need to cover whether changes to the QMS, product ranges etc affect the contract with the PRRC and the responsibilities of the PRRC.

Certain records of the QMS and the technical documentation 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:

- **Batch release documentation:** Audit and/or PRRC approval / approval of the related procedures
- **Technical file and declaration of conformity drawn up:** Sign off on approval page and/or audit
- **PMS obligations met:** Audit and / or add PRRC to circulation list of PMS Report or PSUR / approval of related procedures.
- **Vigilance obligations met:** Audit and / or requirement to sign off on every vigilance report / approval of related procedures

- **Statement in Annex XV that investigational devices conform with GSPRs in Annex I:** PRRC approval.

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 different types of devices, the complexity of those devices and the production volumes to be released. Whatever methods are chosen, it is important that the PRRC creates documented evidence of how they have fulfilled their responsibilities.

4.4. Organisational interface with the organisation

The PRRC is required to "ensure" that activities are carried out or obligations are met and is not required to perform these activities themselves. In order to achieve this, they will often need to liaise with other departments such as;

- **Manufacturing / Quality Assurance**: for ensuring conformity of devices / batches released
- **Regulatory Affairs**: for verification of technical documentation / Vigilance reporting / PMS
- **Sales & Marketing**: for appopriateness of data collected for PMS
- **Design & Development**: for inclusion of General Safety and Performance Requirements of Annex I of MDR / IVDR in the design input requirements and the statement regarding investigational devices / technical documentation.

It is imperative that the PRRC has a direct line of communication with the relevant people to facilitate these activities.

4.5. PRRC reporting lines

The role of PRRC will probably be most effective if they report directly 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 their obligations under MDR. One way to demonstrate this would be to have the PRRC participate in Management Reviews.

If appropriate, and if they comply with the minimum qualifications required, a CEO can be designated as a PRRC, for example if they are the only one with the relevant qualifications in a very small company. However it would be prudent to demonstrate their impartiality. For example, TEAM-PRRC suggests:

- To write two different job descriptions,
- To specify that if both functions are performed by the same person, the decisions of the PRRC may take precedence over those of the CEO.

- To ensure that the actions of the CEO in their role of the PRRC are included in the internal audit.

From this point of view, outsourcing to a third party is a neutral solution, but note that it is not mandatory.

5. The liability of the PRRC

This topic would benefit from further clarification across the EU. The penalties for a manufacturer not properly fulfilling their obligations depend on how infringements are detailed within the national law of each Member State.

For the PRRC who has the 'responsibility to ensure' Article 15 of the regulations does not mention liability in the context of the PRRC other than Article 15.5 which states that the PRRC "shall suffer no disadvantage". This is taken to mean that the individual should not be excluded from rewards, bonuses or promotions if batches are rejected or nonconformities are raised within the QMS regarding the compliance of technical documentation, PMS or vigilance procedures etc. This assumes that PRRC employees are protected under EU employment law.

Manufacturers 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 responsibitilies and the regulations do not state that the PRRC can be held personally liable.

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

5.1. Penalties

The regulations leave it to the Member States to determine the penalties applicable to infringements of its provisions. The Member States should have notified these penalties to the Commission no later than three months before the date of application of the Regulations.

TEAM-PRRC Position:

TEAM-PRRC regrets this information is not shared in a single location. TEAM-PRRC is also of the opinion that a company may be found in non-conformity with Article 15 but not a PRRC directly.

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, it is vital that objective evidence is generated to demonstrate what was carried out. The PRRC must establish that all relevant procedures are drawn up, implemented and maintained. This can be further supported by verifying the presence of a valid third party certificate for the quality management system and by being part of the approval process for procedures. If certification is not required an audit can be done by the PRRC themselves to verify all relevant forms and templates exist. Execution of procedures can be verified on sampling basis, as applicable.

6. Conclusion

The requirements for the responsibilities of a PRRC differ depending on the type, size and location of the economic operator and on the range of devices covered. 'Manufacturers' includes those importers, distributors and producers of systems and procedure packs that are acting as manufacturers – i.e. performing some value-added process on devices already placed on the market. Manufacturers of all types are required to appoint a PRRC for all classes of devices. Where the PRRC is responsible for ensuring some parts of the regulatory compliance of the manufacturer, the manufacturer is responsible for the safety and performance of their devices and their compliance.

Whilst the responsibilities of the PRRC can be compared to those of similar roles in other regulated industries, TEAM-PRRC recognizes that they are different and certainly new to many regulatory affairs staff in the medical device industry. For this reason it is the aim of TEAM-PRRC to position itself to provide a supportive environment to its members which comprise PRRCs, those who would like to become PRRCs and those who need to employ PRRCs. Where there is a lack of clarity or simply omissions in the requirements and guidance available so far, TEAM-PRRC is working to find answers.

7. Presentation of the Association

TEAM-PRRC has been established as a non-profit organisation 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.

7.1. 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 organisation towards more harmonisation

7.2. 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
- Member of the Board – Ronald BOUMANS
- Secretary – Jean-Louis Divoux
- Treasurer – Daniel Petit

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

7.3. Who may join the association?

There are three ways to join the association:

- 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.

- 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 organisation in the clarification of specific quality or regulatory questions.
- Sponsorship: All organisations (companies) who want to support our association.

7.4. Benefits of Membership

The members can benefit from:

- Access to insurance companies who understand the role of PRRC,
- Legal assistance when drafting and inssuing a contract
- Access to training organisations 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.