Person responsible for regulatory compliance (PRRC)

An overview of the requirements and practical considerations

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28 July 2021

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Medical Device White Paper Series

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

An overview of the requirements and practical considerations

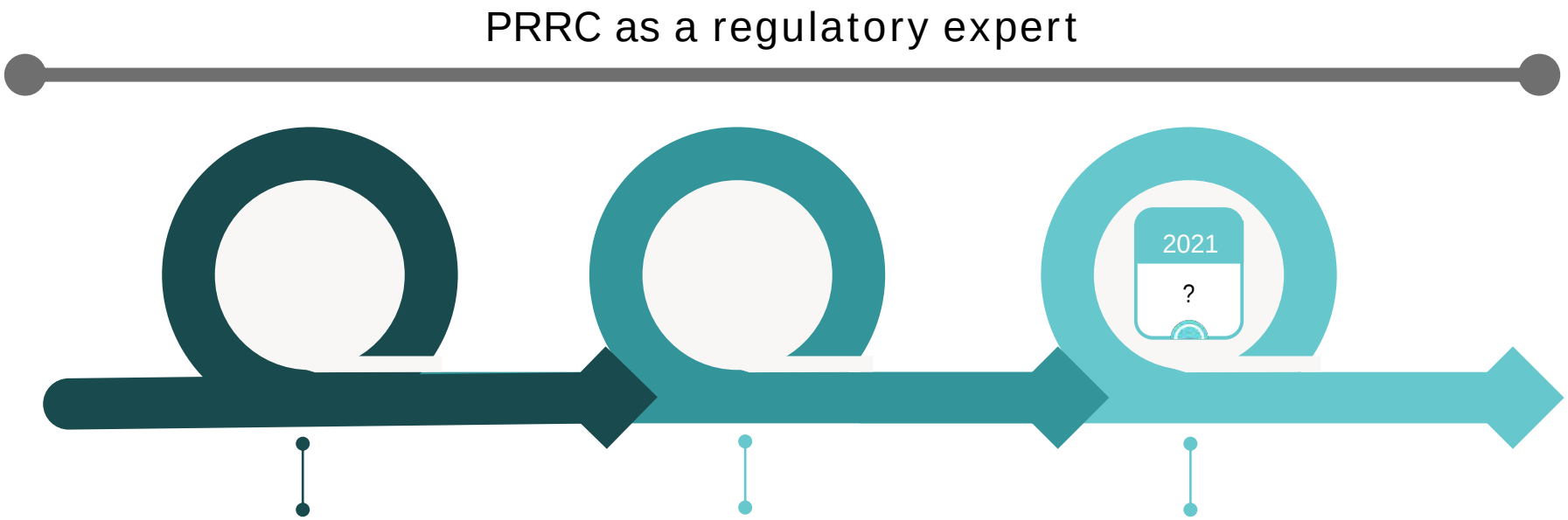
Authors - Anne Jury, Maddalena Pinsi

- Information presented within this webinar is based on our current understanding of the Regulations
- Subject to change

AGENDA

- Background
- Roles and responsibilities of the PRRC within a manufacturer
- Roles and responsibilities of the PRRC within an Authorised Representative
- Qualifications of the PRRC
- Who needs to appoint a PRRC
- Where can the PRRC be located?
- Practical considerations

BACKGROUND



Ensure compliance

Ensure the compliance of released devices, as well as the post-market surveillance (PMS) and vigilance activities concerning those devices (MDR recital 34, IVDR recital 33)

PRRC in AR

For manufacturers based outside the EU, the PRRC in the AR ensures a secondary control is conducted to verify regulatory compliance of the devices

MDCG 2019-7 rev.1

MDCG 2019-7 is expected to be revised sometime in 2021

Devices under the Regulations

Legacy devices* (under the Directives)

We think PPRC is required for legacy devices too since the "Guide to Using EUDAMED - Actor registration module for economic operators" lists it as mandatory field, but this migth be subject to change

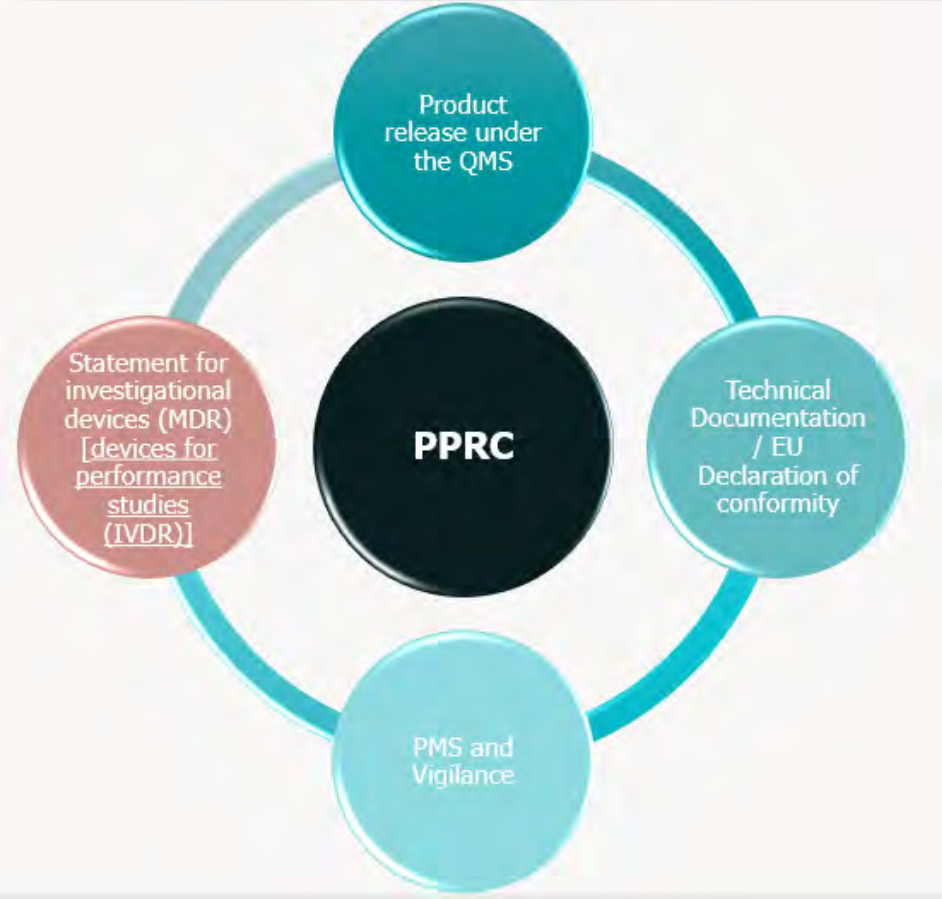
**"Legacy devices" defines as per MDGC 2019-5 and MDCG 2021-13*

Roles and responsibilities of the PRRC

Can the PRRC also be the Quality Manager in a company?

a. Yes
b. No
c. Don’t know

ROLES AND RESPONSIBILITIES OF THE PRRC WITHIN A MANUFACTURER



3(a) the conformity of the devices is appropriately checked in accordance with the QMS under which the devices are manufactured, before a device is released

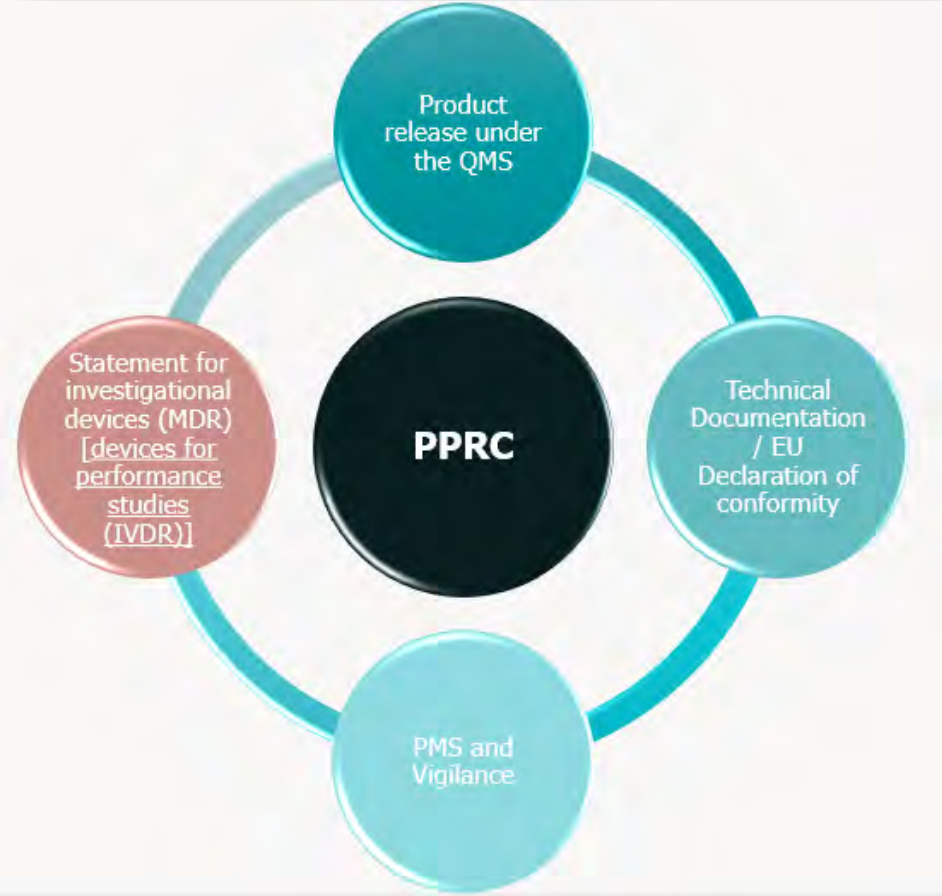
3(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date

3(c) the post-market surveillance obligations are complied with in accordance with Article 10(10) [10(9)]

3(d) the reporting obligations referred to in Articles 87 to 91 [82 to 86] are fulfilled

3(e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued [in the case of 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 Annex XIV is issued]

ROLES AND RESPONSIBILITIES OF THE PRRC WITHIN A MANUFACTURER

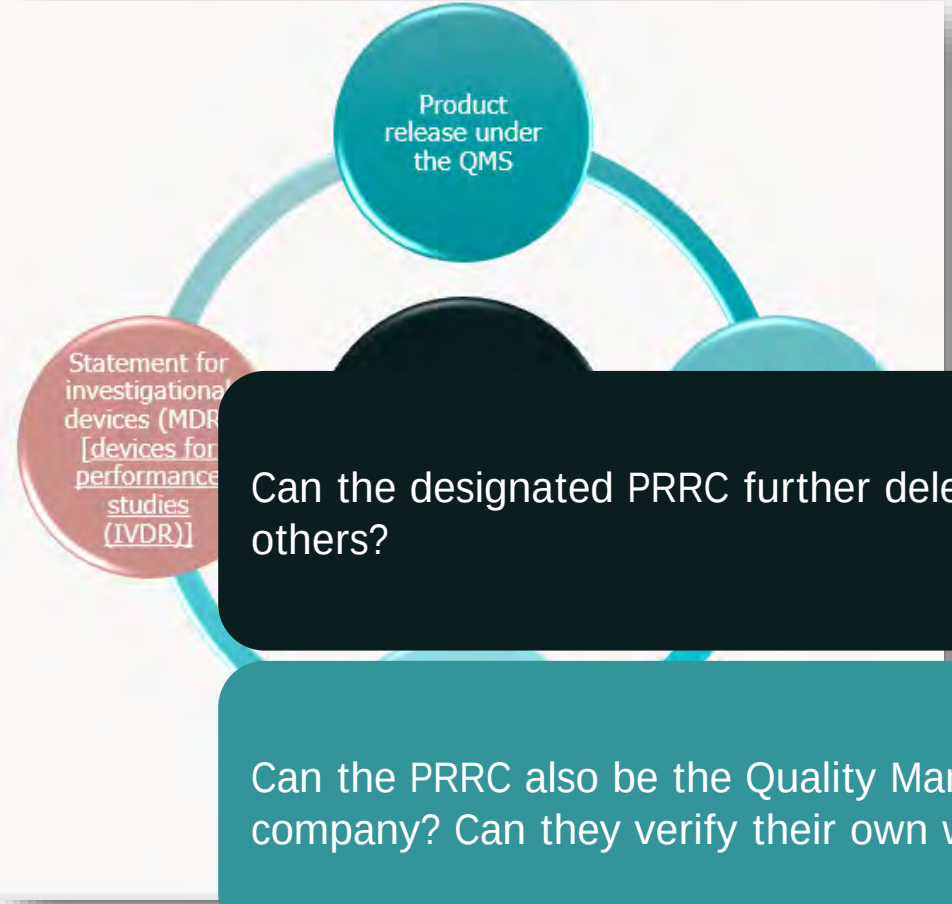


The PRRC is responsible for ensuring that these duties are performed: there is no requirement for the PRRC to actually perform these tasks themselves.
The PPRC has responsibilities in terms of verification and oversight.
In case of delegation, the related methods of verifications by the PRRC are expected to be stated in the QMS documentation.

An established QMS is vital for supporting the PRRC in this role, including appropriate procedures to be in place to control the execution of the responsibilities

It is expected that the responsibilities of the PRRC are documented and accepted by the person and that evidence of them fulfilling the qualification requirements are provided.
It is also expected that the PRRC has full access to relevant documents and records, in order to fulfil the tasks best.

ROLES AND RESPONSIBILITIES OF THE PRRC WITHIN A MANUFACTURER



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The PPRC has responsibilities in terms of verification and oversight.
In case of delegation, the related methods of verifications by the PRRC are expected to be stated in the QMS documentation.

Can the designated PRRC further delegate to others?	It could be acceptable as long as it is documented. Areas of responsibilities shall be stipulated in writing.
Can the PRRC also be the Quality Manager in a company? Can they verify their own work?	The regulations do not prohibit this

PRRC WITHIN A MANUFACTURER

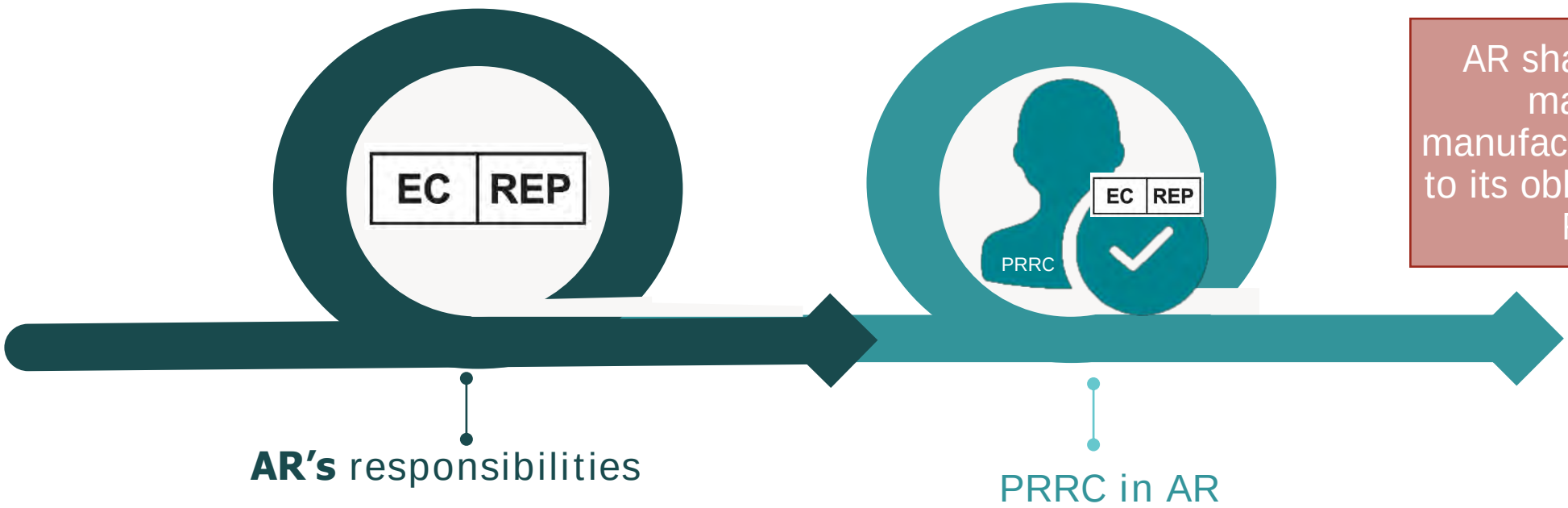
	MDR [IVDR] Article 15 text	Responsibilities of a manufacturer
	3(a) the conformity of the devices is appropriately checked in accordance with the quality management system under which the devices are manufactured, before a device is released	"The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and action necessary to achieve compliance with the provisions of this Regulation" (Article 10(9)) [10(8)].
	3(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date	Manufacturers "[of 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)) [10(5)]. The requirements for the Technical Documentation are in Annex II and Annex III of the MDR and IVDR, while Annex IV of the Regulations lists the information to be included in the EU declaration of conformity.
	3(c) the post-market surveillance obligations are complied with in accordance with Article 10(10) [10(9)]	Manufacturers "of devices shall implement and keep up to date the post-market surveillance system" (Article 10(10)) [10(9)]. The requirements for the post-market surveillance system are described in Article 83 [78] and Annex III.
	3(d) the reporting obligations referred to in Articles 87 to 91 [82 to 86] 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 [82 and 83]" (Article 10(13)) [10(12)].
	3(e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued [in the case of 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 Annex XIV is issued]	Manufacturers shall ensure that "a signed statement by the natural or legal person responsible for the manufacture of the investigational device [for performance study] that the device in question conforms to the general safety and performance requirements 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." (Annex XV 4.1) [Annex XIV 4.1]

ROLES AND RESPONSIBILITIES OF THE PRRC WITHIN AN AUTHORISED REPRESENTATIVE

The PRRC of an AR should be responsible for ensuring that the tasks of an AR as specified in the given mandate (as per Article 11) are fulfilled

- Verification that the declaration of conformity and technical documentation have been drawn up and that, where applicable, the appropriate conformity assessment procedure has been conducted
- Keeping available a copy of the technical documentation, the declaration of conformity and, if applicable, the relevant certificate issued by the Notified Body at the disposal of competent authorities
- Complying with the obligations to register in EUDAMED the AR and AR PRRC details (Article 31 [28] and Annex VI Part A, Section1)
- Verify that the manufacturer has registered UDI information as per Article 27and details of devices registered (Article 29 [26])
- In response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the MS concerned
- Forward to the manufacturer any request by a competent authority of the MS in which the AR has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device
- Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices
- Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated
- Terminate the mandate if the manufacturer acts contrary to its obligations under the Regulation

ROLES AND RESPONSIBILITIES OF THE PRRC WITHIN AN AUTHORISED REPRESENTATIVE



AR shall terminate the mandate if the manufacturer acts contrary to its obligations under the Regulation

AR's responsibilities

Article 11(3h) and 11(6s): if the AR terminates the mandate when the manufacturer acts contrary to its obligations under the Regulations, the AR shall inform the competent authority of the Member State in which the AR is established and, where applicable, the NB that was involved in the conformity assessment for the device

PRRC in AR

Even if not detailed in Article 15, it is supposed that the PRRC in the AR would be expected to ensure that such notification occurs in cases where such issues arise.

WHAT IF THE PRRC ENCOUNTERS A SITUATION WHICH DOES NOT CONFORM TO EXPECTATIONS?

The Regulations do not explicitly state what the PRRC should do (or who they shall notify) in case they encounter a situation which does not conform to expectations

The QMS procedure(s) defining their responsibilities and tasks should also address the actions to be taken in case a non-conforming situation is encountered by the PRRC

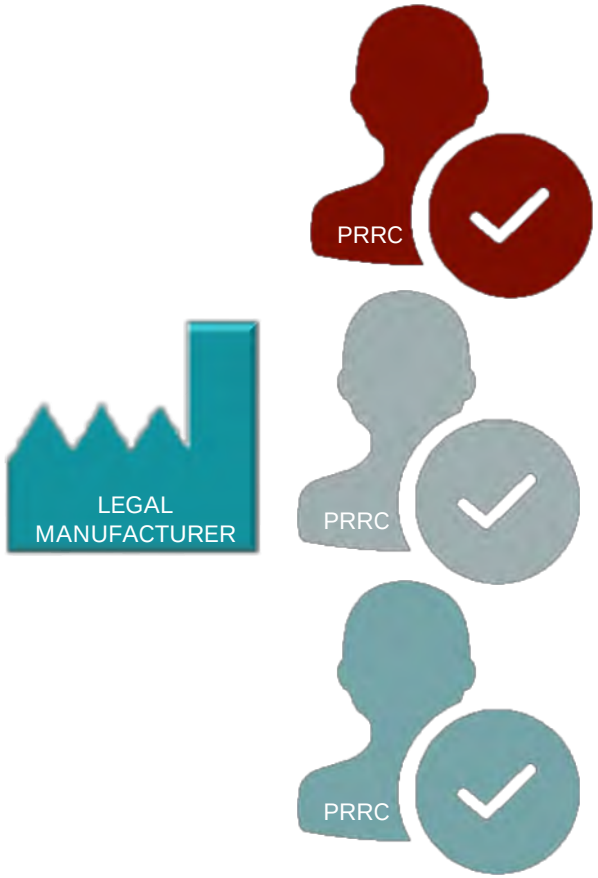
It is important that senior management understands the full scope and responsibilities of the PRRC's role, and gives them the necessary authority and cooperation to resolve any nonconformities that arise

The PRRC shall suffer no disadvantage within the organization
(the PRRC should not be prevented from doing their job)

Can more than one person be appointed as PRRC?

a. Yes
b. No
c. Don’t know

MULTIPLE PRRCs



Ensure technical documentation is drawn up and kept up-to-date

Ensure that the conformity of the devices released is appropriately checked

Ensure the PMS requirements and the reporting obligations are fulfilled

Document the competencies of each PRRCs

Their respective areas of responsibility shall be stipulated in writing (Article 15, clause 4)

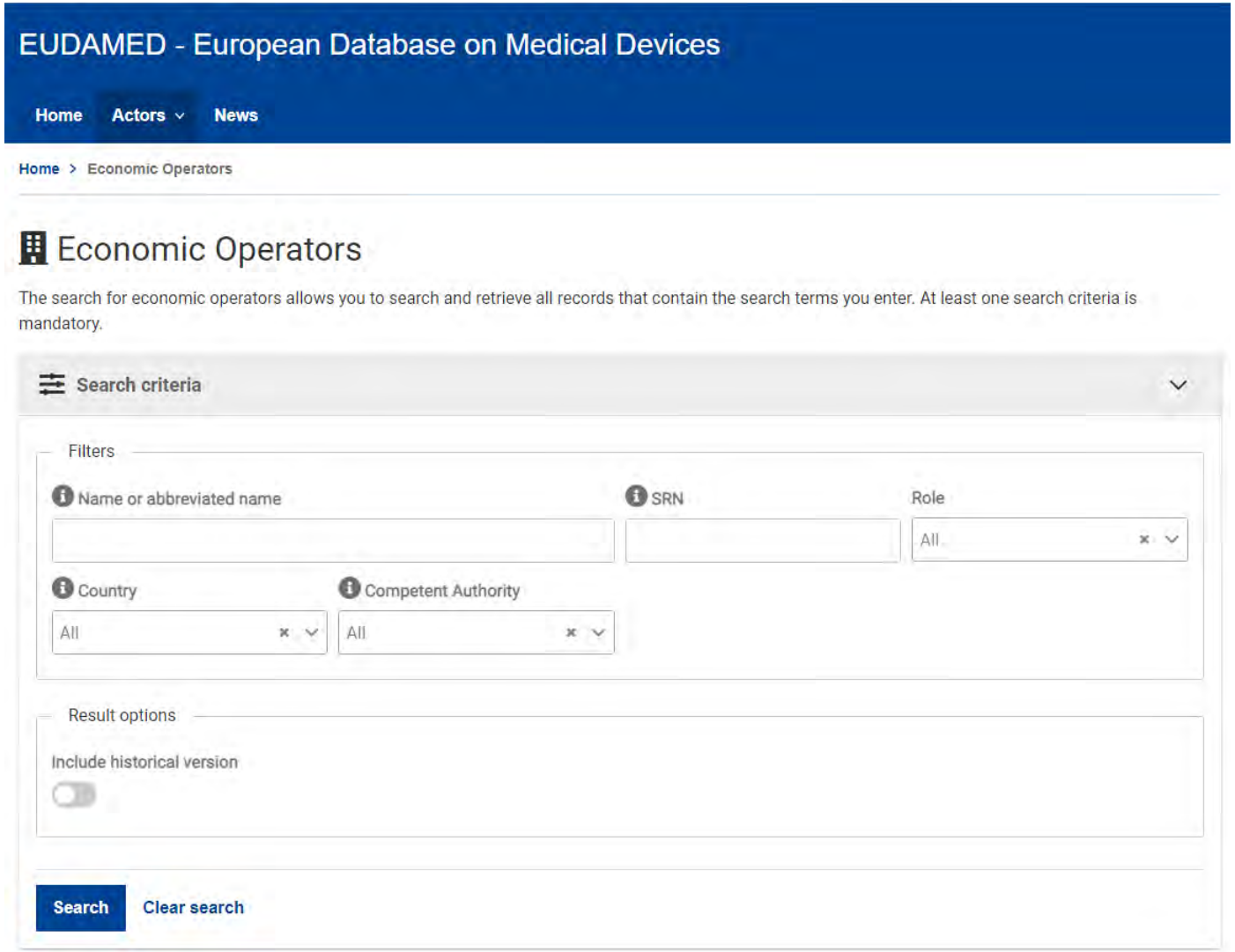
Register in EUDAMED each person who has been appointed as PRRC

Even an AR can have multiple PRRCs to cover one legal manufacturer, as long as their respective areas of responsibility are stipulated in writing

REGISTRATION IN EUDAMED

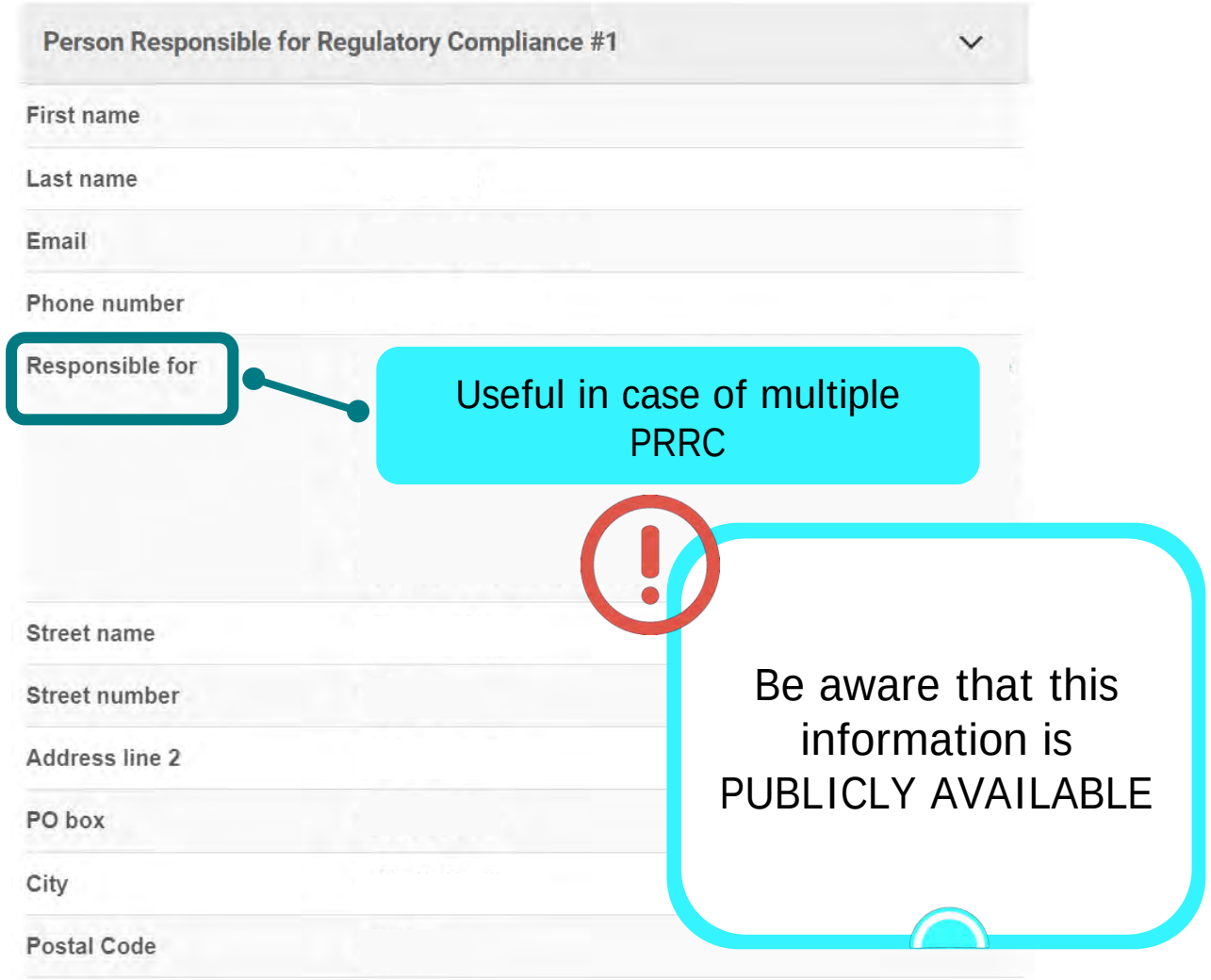
Use of EUDAMED Actor Registration is strongly recommended, but not mandatory until a notice is published in the Office Journal of the EU that EUDAMED fully functional.
Use of EUDAMED will become mandatory six months after the date of publication of the notice in the OJ EU

- EUDAMED Actor registration module now live!!
- Economic operators can now register and get their Single Registration Number (SRN)
- https://ec.europa.eu/tools/eudamed/#/screen/search-eo (search for economic operators)
- https://ec.europa.eu/health/md_eudamed/actors_registration_en (more information about EUDAMED)
- Additional guidance in MDCG 2020-15 and MDCG 2021-13



https://ec.europa.eu/tools/eudamed/#/screen/search-eo

REGISTRATION IN EUDAMED



Qualifications of the PRRC

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QUALIFICATIONS FOR THE PRRC

	QUALIFICATION	PROFESSIONAL EXPERIENCE
OPTION 1	• 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 MS concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline" *(MDR/IVDR)* • Any qualification acquired outside the EU, including any university diplomas or certificates, should have been recognised by an EU Member State as equivalent to the EU corresponding qualification *(MDCG 2019-7)**	• At least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices [in vitro diagnostic medical devices] *(MDR/IVDR)* • The professional experience in regulatory affairs or in quality management systems should be related to the EU requirements in the field *(MDCG 2019-7)*
OPTION 2		• Four years of professional experience in regulatory affairs or in quality management systems relating to medical devices [in vitro diagnostic medical devices] *(MDR/IVDR)*

* The MDGC 2019-7 interpreted this in relation to PRRC within a manufacturer: it is supposed it could be extended to the PRRC within an AR

QUALIFICATIONS FOR THE PRRC

QUALIFICATION

Expected to be recent in relation to EU medical devices legislation *(recent enough to have knowledge of the changes in the EU regulatory environment),* therefore this has to be taken into consideration when appointing the PRRC

relevant scientific discipline" *(MDR/IVDR)*

- Any qualification acquired outside the EU, including any university diplomas or certificates

Manufacturers to be ready to demonstrate the relevant professional experience and to justify their selection of the PRRC

OPTION 2

PROFESSIONAL EXPERIENCE

- At least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices [in vitro diagnostic medical devices] *(MDR/IVDR)*
- The professional experience in regulatory affairs or in quality management systems should be related to the EU requirements in the field *(MDCG 2019-7)*

- Four years of professional experience in regulatory affairs or in quality management systems relating to medical devices [in vitro diagnostic medical devices] *(MDR/IVDR)*

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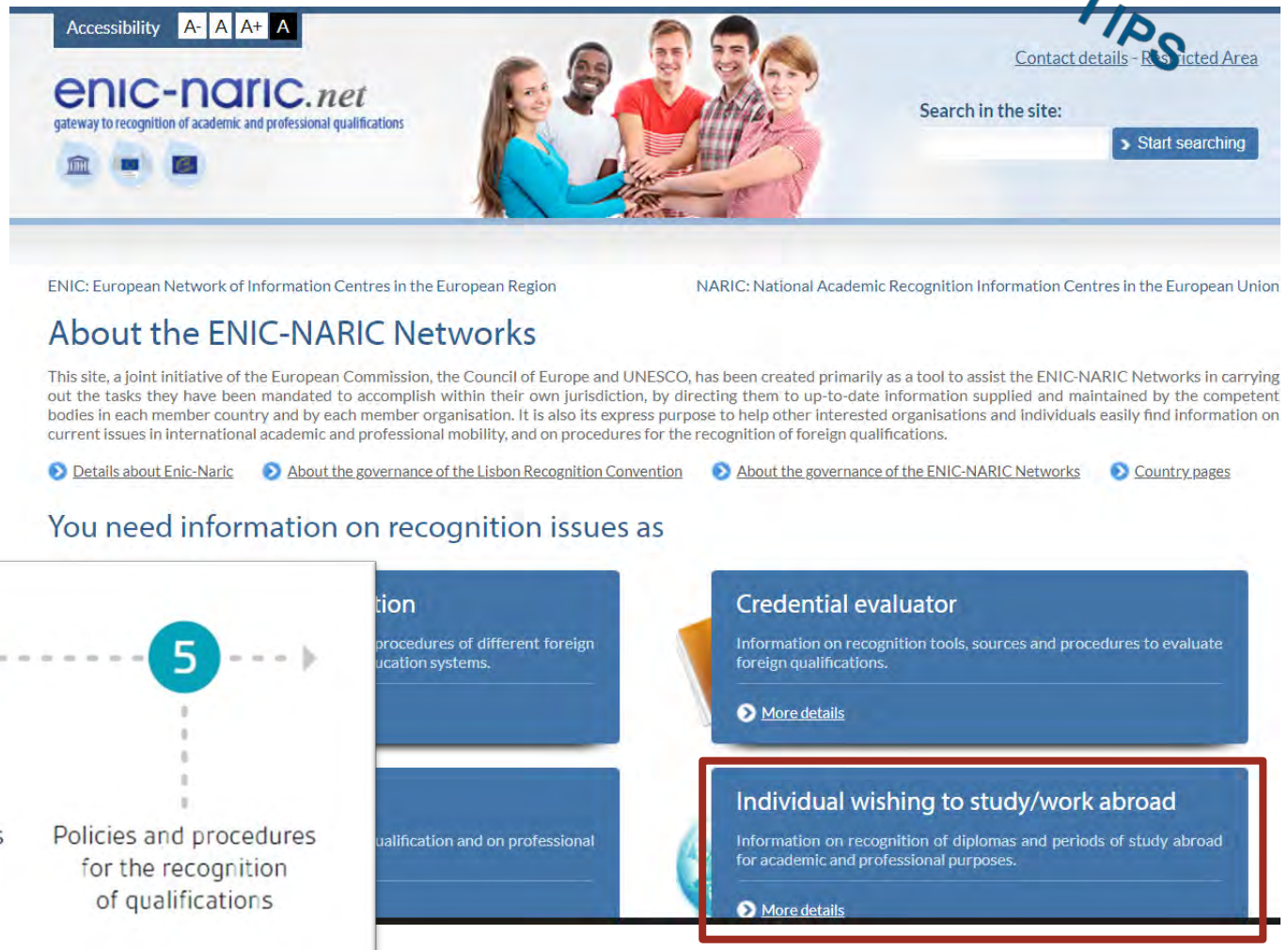
OPTI	Custom-made devices: may demonstrate the requisite expertise referred to in the first option by having at least two years of professional experience within a relevant field of manufacturing	

Recognition of qualifications acquired outside the EU

TIPS

The website for ENIC (European Network of Information Centres in the European Region) and NARIC (National Academic Recognition Information Centres in the European Union) enables the user to find information on procedures for the recognition of foreign qualifications in the different EU member states

https://www.enic-naric.net/



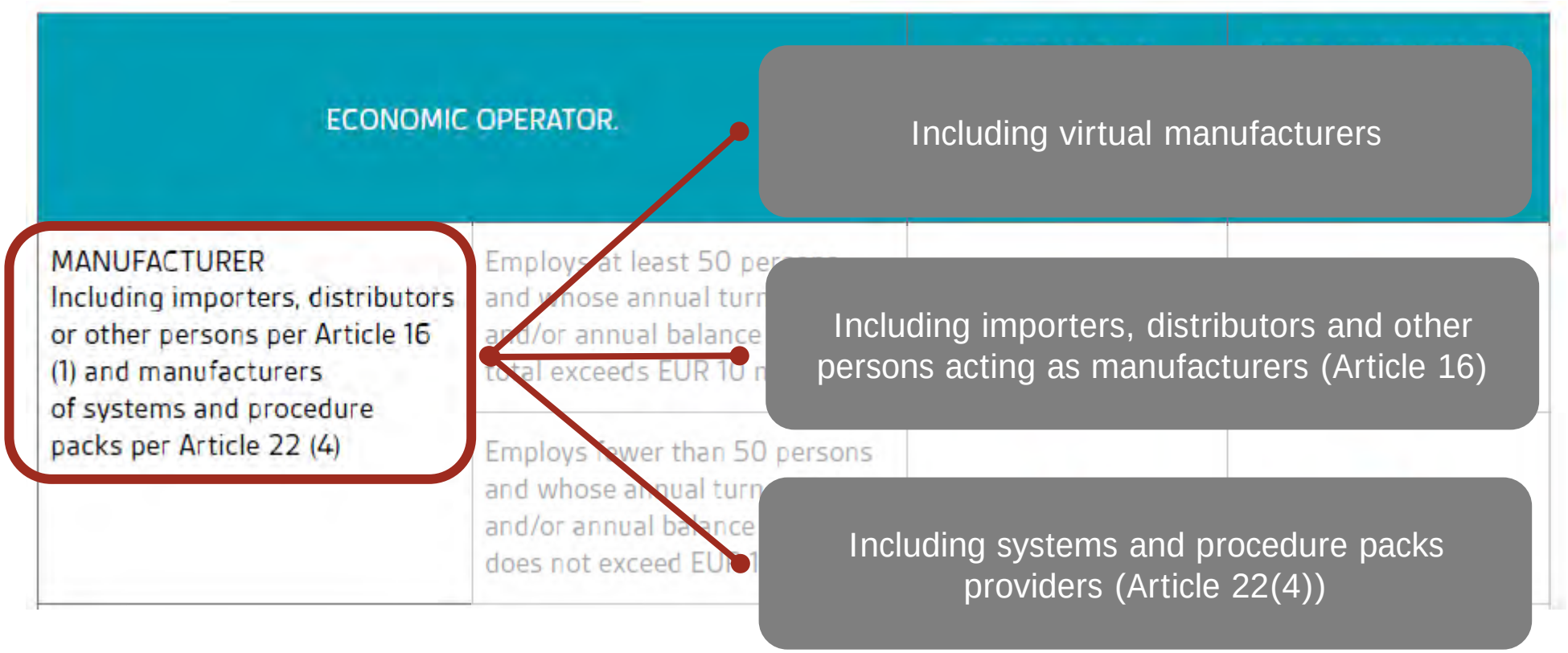
Who needs to appoint a PRRC?

WHO NEEDS TO APPOINT A PRRC?

ECONOMIC OPERATOR.		PRRC WITHIN THE ECONOMIC OPERATOR'S ORGANISATION	PRRC PERMANENTLY AND CONTINUOUSLY AT DISPOSAL (SUBCONTRACTOR)
MANUFACTURER Including importers, distributors or other persons per Article 16 (1) and manufacturers of systems and procedure packs per Article 22 (4)	Employs at least 50 persons and whose annual turnover and/or annual balance sheet total exceeds EUR 10 million	✓	✗
	Employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million	✓	✓

Micro and small manufacturers as defined by the Commission Recommendation 2003/361/EC

WHO NEEDS TO APPOINT A PRRC?



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	Employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million	✓	✓

- PRRC qualifications
- Permanent and continuous availability of PRRC
- How PRRC can fulfil their obligations

Contract in place

In case the responsibilities of a PRRC are subcontracted to a third party, the manufacturer shall demonstrate and document how the legal obligations are met

WHO NEEDS TO APPOINT A PRRC?

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AUTHORIZED REPRESENTATIVE		✓	✓

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AUTHORIZED REPRESENTATIVE		✓	✓

- PRRC qualifications
- Permanent and continuous availability of PRRC
- How PRRC can fulfil their obligations

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WHO NEEDS TO APPOINT A PRRC?

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	Employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total do	✓	✓
AUTHORIZED REPRESENTATIVE			

The PRRC for an AR and the PRRC for an 'outside EU' manufacturer or for a small/micro manufacturer who subcontracted the role cannot be the same person.

The PRRC of a micro or small enterprise and the PRRC of the AR shall not belong to the same external organisation.

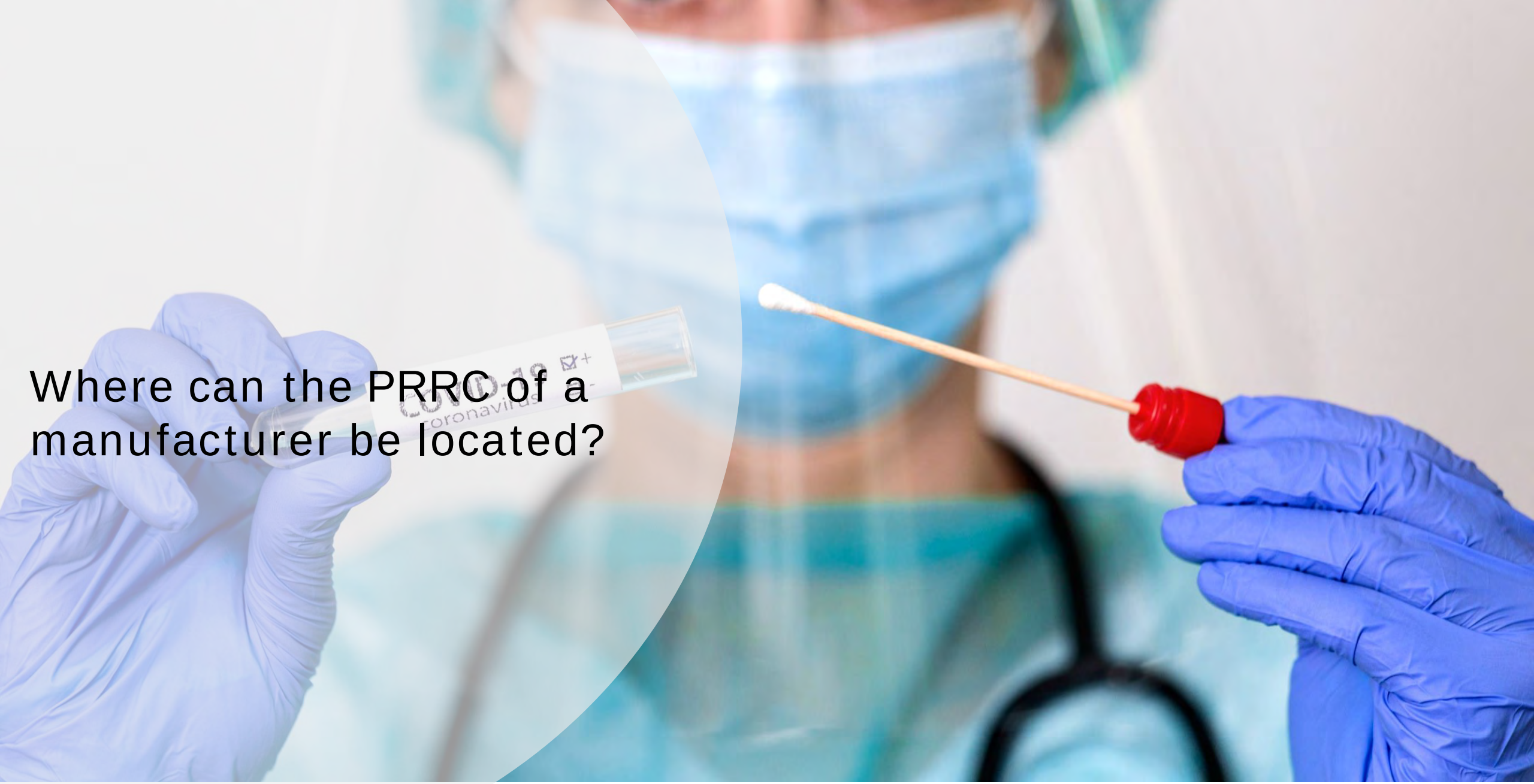
PERMANENTLY AND CONTINUOUSLY AT THEIR DISPOSAL

ECONOMIC OPERATOR.		PRRC WITHIN THE ECONOMIC OPERATOR'S ORGANISATION	PRRC PERMANENTLY AND CONTINUOUSLY AT DISPOSAL (SUBCONTRACTOR)
packs per Article 22 (4)	Employs fewer than 50 persons		
AUTHORIZED REPRESENTATIVE		✓	✓

MDCG 2019-7: When the PRRC is part of an external organisation, the contract with the economic operator should lay down provisions so as to ensure the permanent and continuous availability of that party

Third party PRRC is expected to prove they can be permanently and continuously at disposal of the various companies they are in agreement with

Where can the PRRC of a manufacturer be located?



Where can the PRRC of a manufacturer be located?

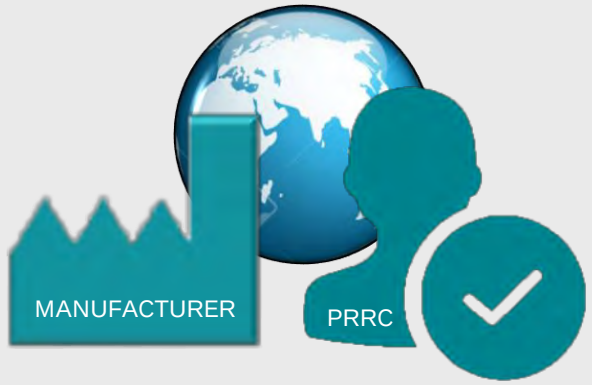
a. Only in the European Union
b. Depending on the region where the manufacturer is based (in the EU or outside the EU)
c. Depending on the Member State where the Authorised Representative is based

WHERE CAN THE PRRC BE LOCATED?

MDGC Guidance 2019-7 underlines the importance of establishing a close linkage of a permanent and continuous nature between the PRRC and the manufacturing activities

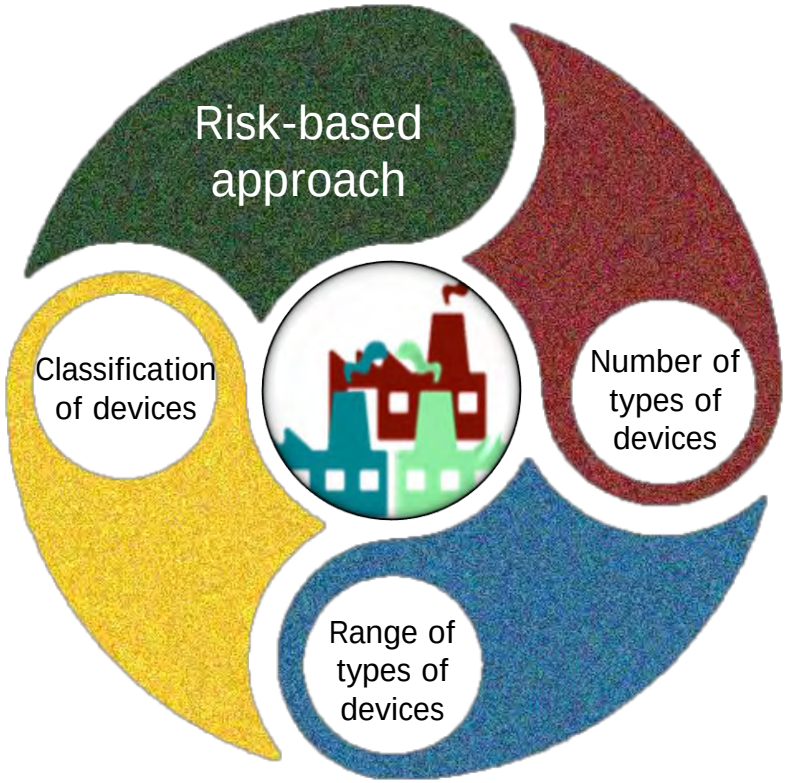
EUROPEAN UNION

OUT OF THE EU



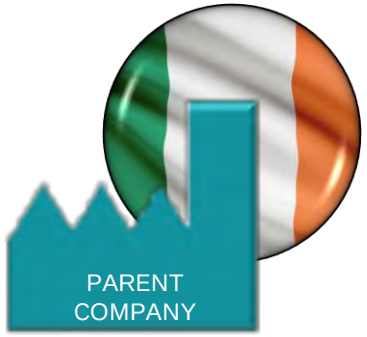
Each legal manufacturer under a parent company must have its own PRRC

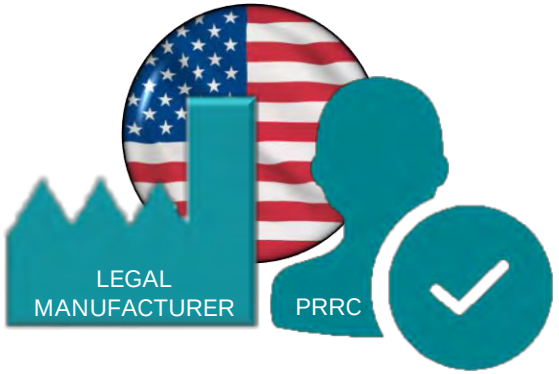
Where and how many PRRCs might be needed



Applicable also in case of multiple manufacturing sites

WHERE CAN THE PRRC BE LOCATED?

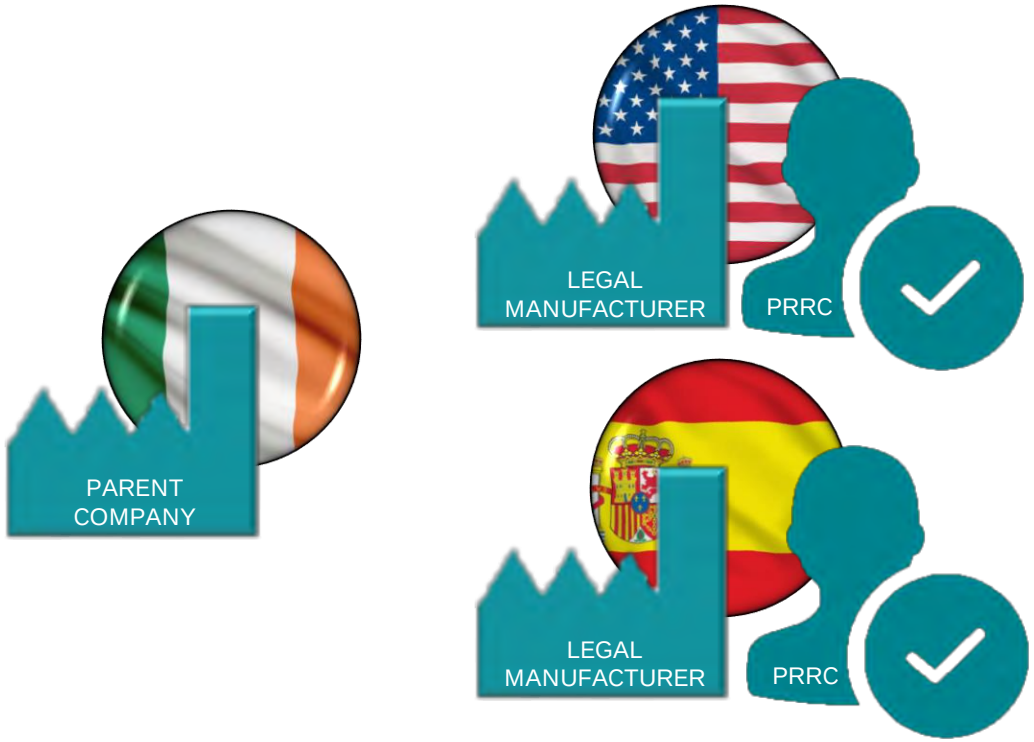




MDCG 2019-7
Organisations with more than one legal manufacturer under the parent company would need to **ensure that each legal manufacturer has its own PRRC**.
In the context of Article 15, the obligation for having available within the organisation at least one PRRC refers to the individual legal manufacturer.

A PRRC should be appointed for each legal manufacturer (separate agreement between each legal manufacturer and the PRRC)

WHERE CAN THE PRRC BE LOCATED?



MDCG 2019-7
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In the context of Article 15, the obligation for having available within the organisation at least one PRRC refers to the individual legal manufacturer.

If there are multiple legal manufacturers under a parent company, can the PRRC be the same person with separate appointment letters for each legal manufacturer or should these be separate persons for each legal manufacturer?

It depends by the single situation (depending on expertise etc...). The Regulations do not prevent this, but there should be separate appointment letters between each legal manufacturer and the PRRC

WHERE CAN THE PRRC BE LOCATED?

Small manufacturer hired a consultancy company based in Ireland to cover PRRC role

The actual PRRC is based in Italy

If PRRC is outsourced to an organisation, which location of the PRRC employed by the outsourced organisation should be considered?
The PRRC home address location or the consultancy company address location?

The PRRC shall be a natural person, not a legal entity, therefore the home address location shall be considered

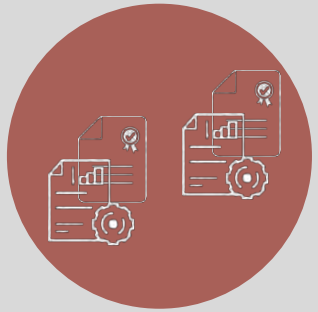
Practical considerations

HOW TO CHECK THE CONFORMITY OF THE DEVICES AT RELEASE?

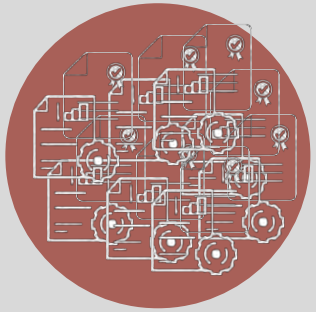
- Oversight of release of devices
- Internal audits of release procedures and batch history/ release documentation
- Periodic sampling of batch release documentation by the PRRC

This is not a finite list, and it is the responsibility of the manufacturer with the PRRC to determine an appropriate process and document it such that it can be subject to external audits

HOW TO CHECK THAT THE TECHNICAL DOCUMENTATION AND THE EU DoC ARE DRAWN UP AND KEPT UP-TO-DATE?



Check each technical documentation
Sign each EU DoC



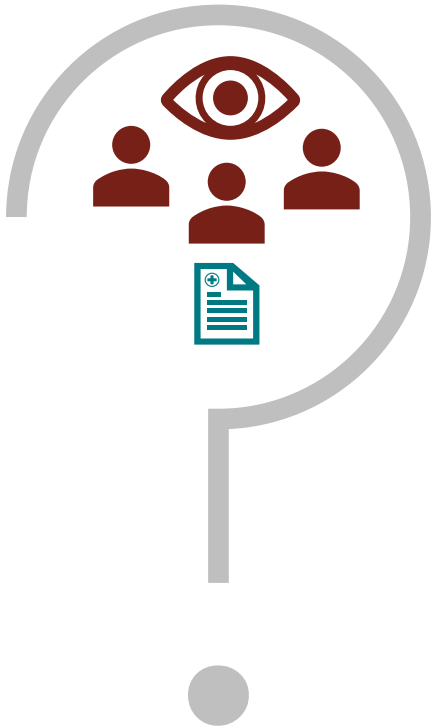
Auditing, sampling, or being an approver of the procedure for this activity

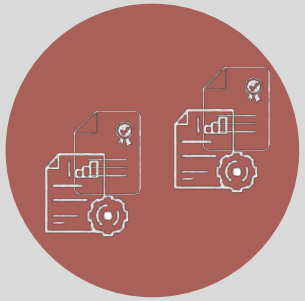
Upon signing the EU declaration of conformity, the signatory makes a binding commitment on behalf of the manufacturer that the device covered by the declaration is in compliance with the relevant legislation.

However, Article 15 does not go as far as saying that the PRRC must sign the EU declaration of conformity, only that they should ensure it is drawn up and kept up to date.

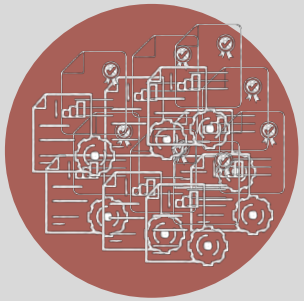
It is the responsibility of the manufacturer with the PRRC to determine an appropriate process and document it such that it can be subject to external audits

HOW TO CHECK THAT THE PMS AND REPORTING OBLIGATIONS ARE FULFILLED?

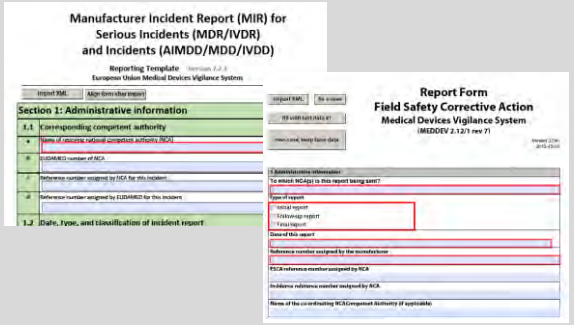




Approver of each PMS plan/report, PSUR



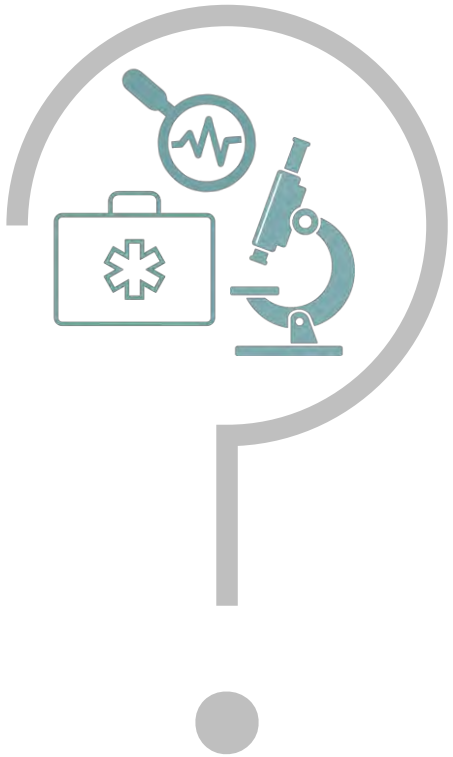
Auditing, sampling, or being an approver of the procedure for this activity



The PRRC could audit the related procedures and make sure that all requirements are adequately covered, including for trend reporting described in Article 88 of the MDR and Article 83 of the IVDR as well as having sight of all serious incidents.

It is the responsibility of the manufacturer with the PRRC to determine an appropriate process and document it such that it can be subject to external audits

WHAT TO DO AS PRRC IF THERE ARE DEVICES UNDERGOING CLINICAL INVESTIGATION (MDR) OR PERFORMANCE STUDIES (IVDR)



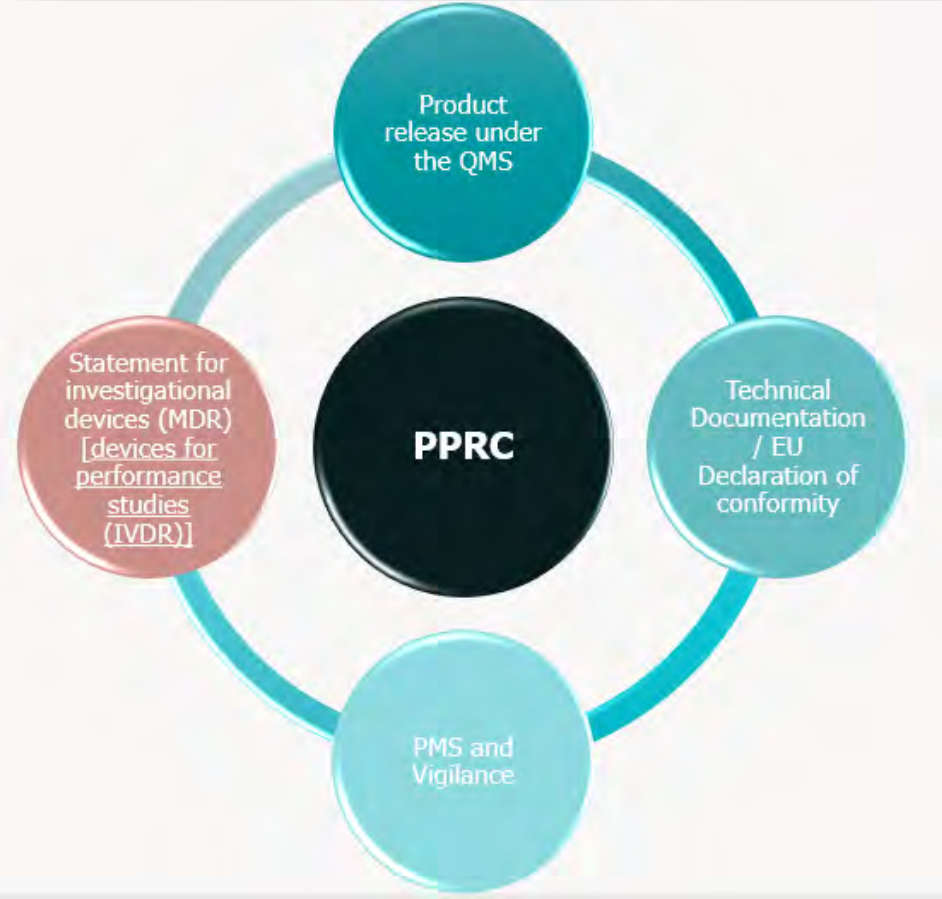
The PRRC should ensure that a signed statement* is issued by the natural or legal person responsible for the manufacture of the investigational device or of the device for the performance study

This statement shall declare that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation or performance study, and that with regard to those aspects, every precaution has been taken to protect the health and safety of the subject

According to the MDR and IVDR there is no specific requirement for the PRRC to fulfill other clinical investigation related tasks, such as being involved in the release of investigational devices or devices for performance studies

** Statement referred to in Section 4.1 of Chapter II of Annex XV of the MDR [Section 4.1 of Annex XIV of IVDR]*

SUMMARY



The PRRC is a critical function and plays an important role in the compliance of the organization

It is important that senior management understands the full scope and responsibilities of the PRRC's role, and gives them the necessary authority and cooperation to resolve any nonconformities that arise

BSI Medical Devices – Use Our Resources

https://www.bsigroup.com/en-GB/medical-devices/resources

Brochures, Guides and Documents

MDR guidance

MDD Best Practice Guidelines >
MDR Best Practice Guidelines >
MDR Mapping Guide >
MedDev 2.7.1 Rev 4 changes >
MDR Conformity Routes >
MDR Readiness Review >

Webinars

MDR Conformity Assessment Routes webinar

MDR - What we know

Download the presentation >

White Papers and Articles

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements...

Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the implications of those differences? What controls are necessary to ensure AI in healthcare is safe and effective?

Medical device clinical investigations – What's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR.

Training Resources

Medical devices regulation (MDR)

Transition from MDD to MDR	1 day
Technical Documentation for CE - Marking	1 day
Requirements of MDR for CE - Marking	1 day
Implementing of MDR for CE- Marking	3 days

Further courses for medical devices manufacturers

Medical Device Single Audit Program (MDSAP)	2 days
ISO 14971 Risk Management	1 day
Creating and Maintaining Technical Files	1 day
Post-market Surveillance and Vigilance	1 day
Clinical Evaluation for Medical Devices	1 day
Process Validation for the Medical Device Industry	1 day
Introduction to Medical Device Software	1 day

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Questions?

Thank you for joining today

Maddalena Pinsi

Regulatory Lead, BSI