



*Your TEAM-PRRC association*

*Newsletter N° 8*

January 26<sup>th</sup>, 2022



### Our president, Elem Ayne, message:

Dear members, partners and all,

I wish all of you first of all Health, Energy, Confidence, Perseverance, Hope, Happiness, Success and the end of the Covid-19 pandemic situation for 2022.

2021 is over and was the year of the application of the MDR (EU) 2017/745. All PRRCs have started their job function, and we started to have some feedback from this new position.

In 2022, we have decided to bring more to our members. We plan many webinars (once per month) and a physical event including presentations from key speakers and round tables to know more about you, doing networking, between October and November 2022, if pandemic situation allows us to realize it and if we have enough people attending this event.

Then, to make viable the Contributors team (the members of the association who want to participate actively to the future projects of the association), we plan to do some round tables only for them and discuss topics where the PRRC is involved.

We remain committed to drive things forward sharing values of equity, integrity, mutual aid and humanity. I also take this opportunity to thank all our members and sponsors who supported us reaching our target in 2021 and are still supporting us towards achieving the strategical target of our association.

Look forward to meeting with you during 2022!

## Editorial

Dear members, bonjour!

This year will mark the application of the IVDR, in 26<sup>th</sup> of May, 2022. Thanks to the application of the MDR, we got some feedback about the role of the PRRC, and Manufacturers of IVD sector are better prepared on how to designate their PRRC. However, due to the less notification of Notified Body (27 Notified Bodies for MDR and only 6 Notified Bodies for IVDR), the European Commission has published a project to facilitate the application of the IVDR:

- The EU IVDR Date of Application has not changed, but the rollout for the transition will. More than 80% of all IVDs in the EU are subject to notified body scrutiny, yet more than 50% do not have one.
- QMS should be ready by May 26, 2022 – PMS, Vigilance, Registration, etc.
- Class A Non-Sterile IVD (no NB interaction-self declared) May 26, 2022
- All New IVDs with no current CE certificate - May 26, 2022
- IVDs with valid IVDD CE certificates - May 26, 2025, but given one year extra to sell off existing products. Ensure no significant change occurs.
- Those IVDs now Class D under IVDR (self-declared previously) - May 26, 2025, but given one year extra to sell off existing products.
- Those IVDs now Class C under IVDR (self-declared previously) - May 26, 2026, but given one year extra to sell off existing products.
- Those IVDs now Class A Sterile & B under IVDR (self-declared previously) - May 26, 2027, but given one year extra to sell off existing products.
- Manufacturers of in-house devices, also known as laboratory-developed tests, have until May 26, 2024, to comply unless they can prove no equivalent product is available. If proof is provided, the European Union will give manufacturers until May 26, 2028, to comply.

This definitively demonstrates the high expectations devoted to that new position by both regulations the MDR and the IVDR. It confirms the need of highly responsible professionals to hold such a major regulatory role in the medical device and in-vitro diagnostic industry.

## *The TEAM*

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## Your association:

Our association has developed its membership with more than 200 members at this date and more than 1000 followers in LinkedIn. We thank all of them to support our association.

We have restructured the organization of the association in 2021 and have welcomed new key people:

- The Board, including:
  - Elem Ayne: President
  - Anne Jury: Vice-President
  - Bassil Akra: Vice-President
  - Jean-Louis Divoux: Secretary
  - Daniel Petit: treasurer
  - Ronald Boumans: Member of the Board
- The Advisory Board, including:
  - Denys Durand-Viel: founder member
  - Corinne Delorme
  - David R Rutledge

We still have the objective to enlarge the organization creating a Contributors team. These following projects will be led by one member of the Board or a member, and contributors can have some meetings about this later. The topics of these projects are:

-  PRRC liability: this will be managed with one of our lawyers
-  Job description template and PRRC's replacement procedure
-  The sanctions
-  EUDAMED
-  Round Tables: the contributor can help us to collect the question
-  Representative on Member States: legal issues, insurance, translating
-  FAQ: these are the Questions & Answers + Forum

To launch the creation of this team, we will organize Round Tables exclusively dedicated for our members and to be able to do networking and meeting each other.

We continue to maintain our close relationship with the relevant stakeholders including but not limited to EU MDCG. We will communicate in your name and provide your feedback by considering the legal text and rules of proportional applications. Towards that aim, we do need your support and inputs. Please send us your questions, your opinion, and your thoughts regarding the PRRC's duties, responsibilities and any other related topics.

The "FORUM" is operational in our site, in your member space. Use the opportunity to exchange with PRRCs and [CHAT!](#) We have also created the **LinkedIn closed group** in LinkedIn called "**TEAM-PRRC Forum**" to facilitate the exchanges between members. This closed group is only open to members of the association.

To recall, the membership is in 2 steps:

- 1- You enter your profile data and we check and approve it
- 2- You pay the membership fee and we give access to your member space

The fees to become an active member are fixed to 250€ for a year and the renewal is fixed to 200€ per year.

Your association is also preparing Round Tables and webinars, and try to negotiate some discount with other organization that can be interesting for PRRCs.

Round tables open to all, free of charge, were a success to make known the association all over the world and to be able to have some feedbacks from PRRC.

Consequently, we will focus this year to webinars and other training program in 2022.

## Short News

- **Position paper – we published the first 2 position papers and we will share the 2 other position papers as soon as possible. Thanks to these Position papers, we have now raised our profile to MDCG.**
- **Specialised PRRC topic webinars will be organized every month or every 2 months**
- **We are discussing to develop a 1-day training for our members into the Board**
- **We are discussing to organize a physical event in Brussels at the end of this year:**
  - **We will realize it if we have at least 40 people, so we need your feedback (a survey will be sent to our members)**
  - **We will keep you in touch, when we will decide about the details.**
- **Call for interest to our members: which topics for the webinars? call for contributors about our project (PRRC liability, templates, etc.)**

## Just for you (our active members)!

This tab ([For U](#)) in our Website includes opportunities and discounts from our cherished sponsors, specifically reserved for our active members. There are attractive prices on training, news feeds and regulation watches, along with documents and templates for your everyday activities... and much more!!



MDlaw annual membership: 43 EUR – 125 EUR – 330 EUR

**TEAM-PRRC member** promotion: **50% on all membership levels**, starting at 23 EUR per month! The discount coupon is shared in membership area {to be used at the checkout of the Store}.



**20% Special discount** for all the webinars to any Team-PRRC member (up to date with his membership fee).



Online **MDR (EU) 2017/745** training course (French only); 6 months continuous access and including 2-hour-live session of Questions and Answers: TEAM-PRRC members special rate: 750€ (instead of 1000 €).

Special 20% discount on one year “Premium” subscription to “Flash de DM Experts” articles.

## And more!



Our sturdy partner MDlaw wrote a very interesting article, on language requirements and sanctions under MDR in Belgium.

They exceptionally agree to share it only for TEAM-PRRC members. Find it here :

[Language requirements & sanctions under the MDR: Belgium](#)

Pdf file will be available in the Active member space.





## Past Events



TEAM-PRRC will be in MEDICA as a visitor, to visit manufacturers of medical devices from 15<sup>th</sup> to 18<sup>th</sup> of November, 2021. It was a great opportunity to make known our association to manufacturers and discuss their situation regarding the application of the MDR (EU) 2017/745.

MEDICA is the world's largest medical trade fair for medical technology, electrical medicine, laboratory technology, diagnostics, physiotherapy, orthopaedic technology and consumer goods. The trade fair takes place once a year in Düsseldorf during 4 days and can only be accessed by trade visitors. Medica takes place at the same time as the world's leading trade fair for medical suppliers, Compamed. Thus, the entire process chain of medical products and technologies is presented to the visitors and makes a visit to both exhibitions necessary for all experts in the industry.

## An update on current changes to MDR, IVDR & Role of the Person Responsible (PRRC)



Our Vice-President, **Anne Jury**, made a presentation at this free-to-attend event on the subject of the role of the PRRC, taken place in November 17<sup>th</sup>.

## A Round Table where we have invited Erik Vollebregt, and presented by Ronald BOUMANS

**TEAM-PRRC Virtual Discussion Table**

**Presenter:**  
 **Ronald BOUMANS**  
Program Manager at EMERGO  
Member of the Board at TEAM-PRRC

**Guest:**  
 **Erik VOLLEBREGT**  
Partner at Axon Lawyers

**Date:** January 11<sup>th</sup>, 2022  
**Time:** 5.00 (pm) – 6.00 (pm) CET  
**Location:** Virtual  
**Language:** English

**Session content**

- 1) Presentation of TEAM-PRRC
- 2) Round Table – exchange with attendees
- 3) Q&A

**FREE OF CHARGE, OPEN TO ALL (limited places)**

You can prepare and send your questions in advance to [inform@team-prrc.eu](mailto:inform@team-prrc.eu)

**Registration required** : please go to the link provided

In January 11<sup>th</sup>, TEAM-PRRC has organized a Round Table, free of charge and open to all, presented by Ronald BOUMANS, member of TEAM-PRRC Board and Program Manager at EMERGO, and Erik VOLLEBREGT was our guest.

This session demonstrated that the PRRCs are still searching for their role and responsibilities.

TEAM-PRRC will continue to provide Round tables session to be able to help PRRCs answering their questions about their daily activities.

To come



## Virtual 6th EAAR Annual Conference on New Medical Device Regulations (RMD2022).

(2-3 February 2022). [>> MORE INFORMATION <<](#)

Our members can benefit from a discount. You can ask your promotional code to [inform@team-prrc.eu](mailto:inform@team-prrc.eu)



**Elem Ayne**  
President

**Anne Jury**  
Vice-President



[www.team-prrc.eu](http://www.team-prrc.eu)



TEAM-PRRC webinar (in [ENGLISH](#)) planned for 8<sup>th</sup> February, 2022 at 6.00 pm CET – [dedicated to members.](#) >>>> [ATTEND](#)

The presenters Anne Jury and Elem AYNE will share with you more explanations regarding :

- 1) **Position Paper N°1: qualifications required to become a PRRC**
- 2) **Position Paper N°2: contracts and location**

There will also be time for Q & A to exchange with members.



TEAM-PRRC webinar (in [ENGLISH](#)) planned for 16<sup>th</sup> February, 2022 at 5.30 pm CET – [free of charge and open to all.](#) >>>> [ATTEND](#)

This is a webinar about **Cybersecurity and the role of the PRRC**, presented by Cécile Théard-Jallu, a healthcare lawyer.

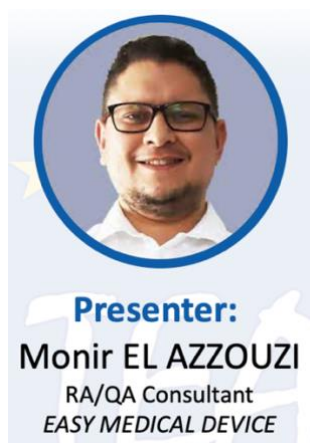
This is the opportunity to ask all your question about Cybersecurity and the PRRC to a lawyer.





TEAM-PRRC webinar (in [ENGLISH](#)) planned for 22<sup>th</sup> March, 2022 – [dedicated to members.](#) >>>> The link to attend will be shared by email and on LinkedIn later.

This will be a new webinar about the **clinical investigation** presented by Carole Robin, a member of our association and an expert in Clinical Investigation.



TEAM-PRRC webinar (in [ENGLISH](#)) planned for April 2022 – [dedicated to members](#) >>>> The link to attend will be shared by email and on LinkedIn later.

This will be a new webinar about **Vigilance** presented by Monir El Azzouzi from Easy Medical Device.

Vigilance is one of the most important part of the PRRC's role. This webinar will bring you all the information that you need to know as a PRRC.

*Webinar*

TEAM-PRRC webinar (in [ENGLISH](#)) planned for April 2022 – [dedicated to members.](#)

We received many questions about **the sanctions**. That's why, we planned a webinar about that topic. This webinar is led by Carole Robin, from our Contributor team.

*Webinar*

TEAM-PRRC webinar (in [ENGLISH](#)) – dedicated to members.

As you know, TEAM-PRRC has negotiated an insurance dedicated to PRRC's role. We thought that it would be useful to organize a webinar with the insurer. This will be the opportunity to understand the PRRC insurance proposed to members, and all risks associated to our job position. This session will be planned as soon as possible.

*Webinar*

TEAM-PRRC webinar (in [ENGLISH](#)) – dedicated to members, [about IVDR.](#)

As you know, 26<sup>th</sup> of May, 2022 is the year of the application of IVDR. That's why it will be important for us to propose to our members a webinar about that regulation and the PRRCs for IVD sector. **This session will be planned as soon as possible.**

As you can see in this Newsletter, we have already planned 7 new webinars to bring our members the latest information. Join us now and you could attend all these webinars, with the opportunity to get the answers to all your questions. Look forward to meeting you!!

A big thanks to our sponsors: visit them on our website!



We wish all medical devices actors a good year ahead for the application of the IVDR and all the best for the PRRCs in their new function.

That's all for this issue of YOUR association newsletter.  
Hope you enjoyed. Hear from you very soon.

**The MANAGEMENT TEAM**