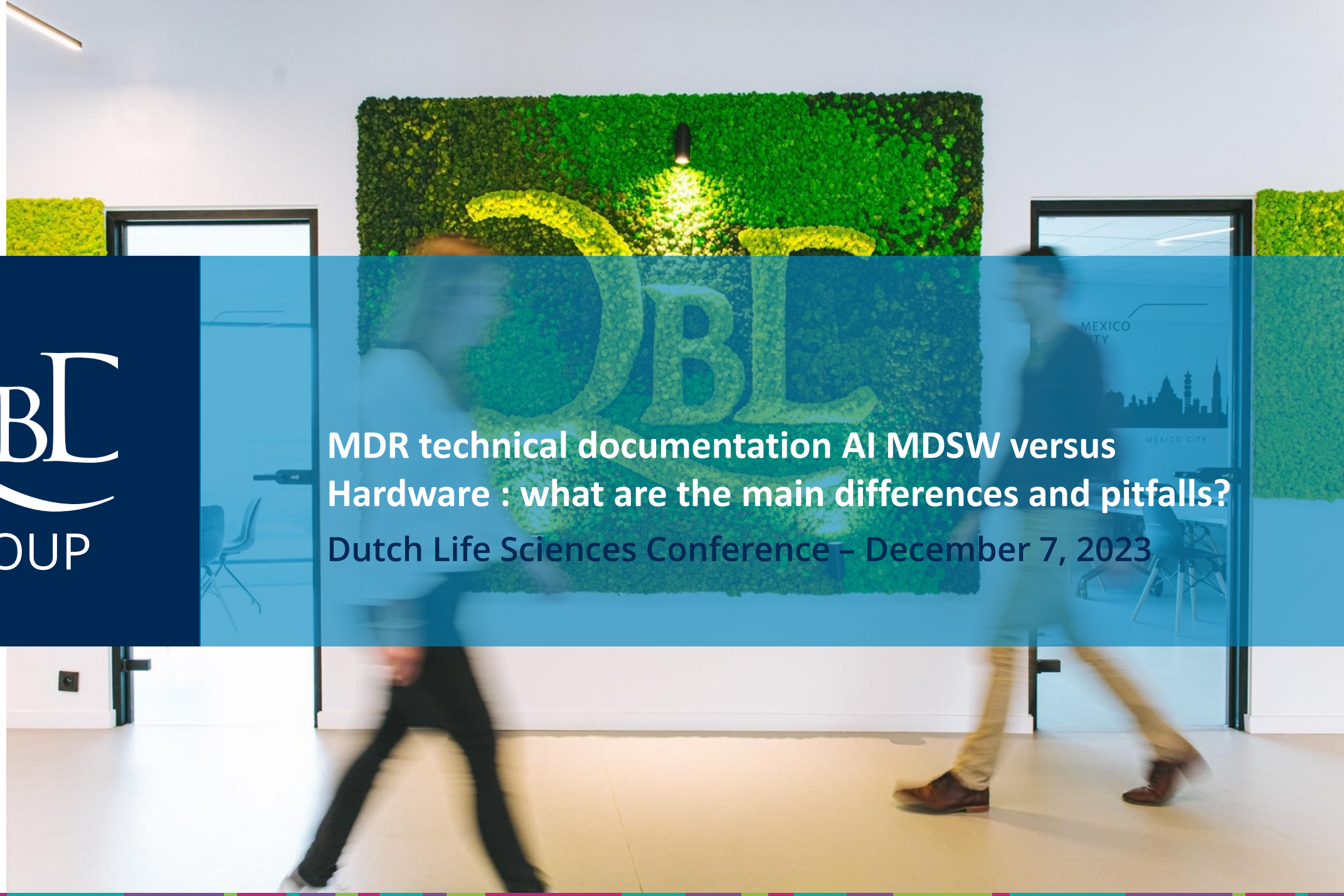

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MDR technical documentation AI MDSW versus Hardware : what are the main differences and pitfalls?

Dutch Life Sciences Conference – December 7, 2023

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Introduction

Directive to Regulation

EU (MDR) 2017/745: Medical Device Regulation

EU (IVDR) 2017/746: In Vitro Diagnostic Regulation

Both delayed to avoid unnecessary disposal of MDs/IVDs on the EU market

Directive extension is under strict requirements (Regulation (EU) 2023/607) to avoid the same issue as in 2021.

Not enough NB certified - NB overloaded not able to review Technical documentation on time

The MDD extension is only to give more time to NBs for reviewing documents - not for Legal Manufacturer as :

- The manufacturer is required to put a QMS in place no later than 26 May 2024; and
- The manufacturer has lodged a formal application in accordance with the EU MDR for conformity assessment no later than 26 May 2024, and the notified body and the manufacturer have signed a written agreement no later than 26 September 2024.

EUDAMED delayed again ➔ up to 2027

RA framework: moving target

Importance of the regulatory watch

Regulatory environment is not static since 2017:

- more and **more countries are regulating** MDs
- **more products are concerned** by the MDR and IVDR (higher risk classification, accessories, Annex XVI)
- Update of many standards especially linked to SW, and related to MDR requirements
- MDCGs not mandatory but most of the time NBs consider them as mandatory or strongly suggest to follow them
- AI Act: how to deal with it if significant changes are forbidden by the extension of MDD certificate
- More to come about AI as many working groups are working on it to define how to regulate AI.

AI Act

Will be published soon

AI Act Is applicable for all fields that can use SW AI: it is very broad and general.

AI Act considers MDSW as High-risk AI system because they are products submitted to EU Harmonization legislation and require a third-party conformity assessment (NB)

NB have an AI guideline very detailed for each part of the QMS and the TD.

Guideline for AI for medical products (johner-institute.com) (which was a cooperation between several NB's and Johner Institute)

Notified Bodies

Not available

Most of them didn't accept any new customers:

- Overloaded
- Priority to current customers
- Priority to urgent products that have a direct impact on major population health issues

Other issues with NBs

- Can only review products for which they are qualified (not all NBs can review all MDs): NANDO is providing all info about it
- Timeline to get a quotation: 2-3 months at minimum- this is critical for manufacturers who want MDD extension
- Review not always harmonized between different NB
- Price! MDR review much more expensive than under MDD.

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MDR submission what to think about?

Is it more difficult?

No BUT :

- Requirements are **more stringent and explicit**
- MDR requirements are not only for the manufacturer but **also for the NBs**
- Additional requirements for the **Quality Management System** which are not in the ISO 13485
- Reinforcement of the **Traceability** (Usage of EUDAMED and UDI)
- Implementation of **unannounced audit** (always be ready)
- Reinforcement of the **Post Market Surveillance** (Vigilance and follow-up on long term)
- New responsibilities for **Economic Operators** (EC-rep, Importer and Distributors)

Manufacturers of Class I product inspected by Competent authorities as no NBs involved

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About timeline…

As there are more requirements, it requests more time to create compliant technical documentation .

QMS audits longer

Technical Documentation review lasts at least 9 - 18 months depending on the classification and the quality of the documentation.

In addition, and if applicable microbiologic audit / critical supplier audit…done by NB as well

Importance of RA plan/Strategy

More and more important to reach the EU market or any other

As it takes more time to reach a product certification either for a legacy device or for a new one it is more and more important to have regulatory strategy plan.

- Well defining which countries are the target
- What sequence: EU first or else?
- Which product in which sequence if there are many legacy products.
- Prepare a good gap assessment: not only for MDR but also for all new standards/guidances versions impacting your products.

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Budget wise

Avoid surprises

Reaching the Certification takes more time… it has a cost impact

Clinical Evaluation: may involve additional costs

- often more data are required either clinical or literature
- is involving Physicians for review

QMS and Technical Documentation audits by NBs: more expensive than before (2 to 3 times more in some cases)

Unannounced audits to be paid

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What remains

The goal is to put a Safe and Performant MD on the Market.

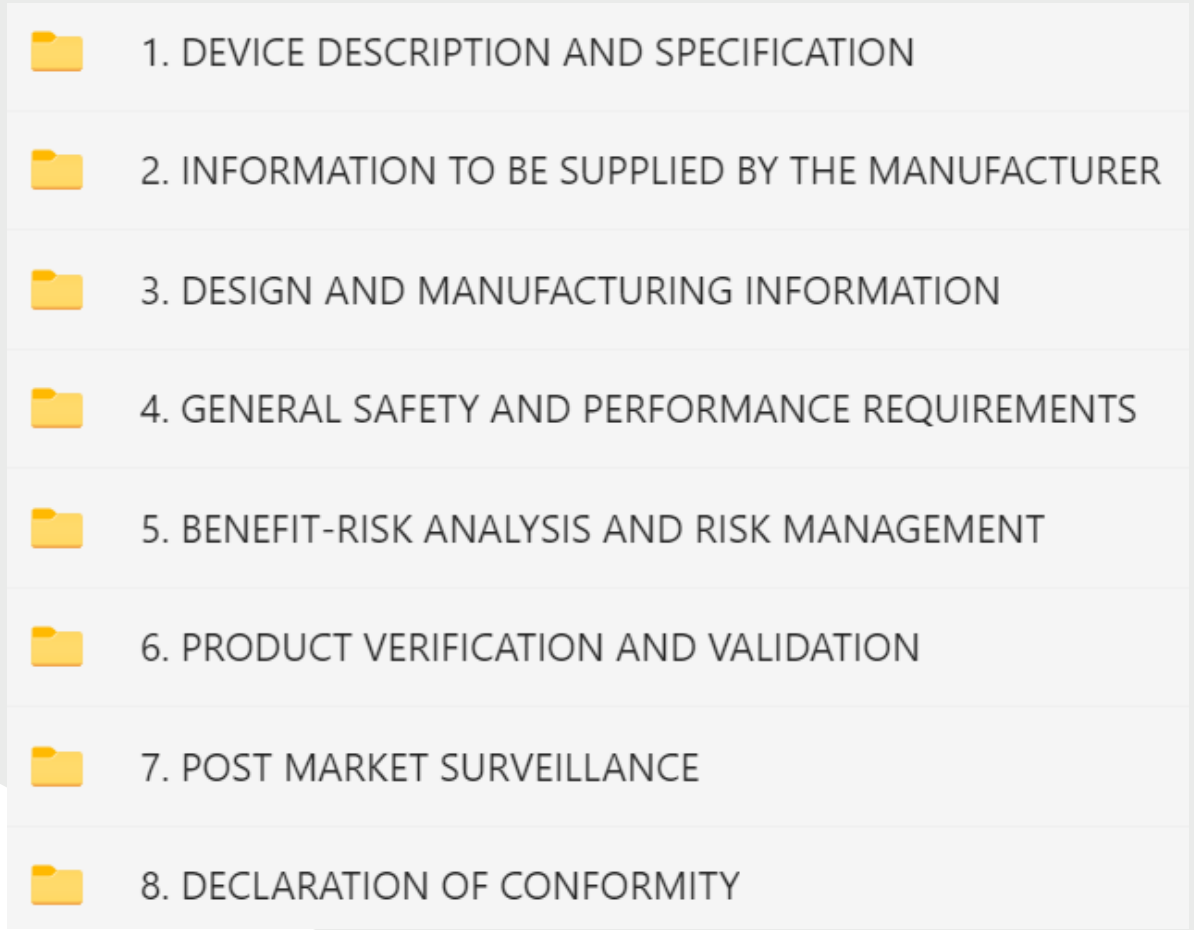
Ensuring that the benefits of device outweigh the risks of it.

The General principle to put a MD Product on the Market by having:

- a Quality Management system in place
- a Technical Documentation

Technical Documentation

Starting point: Technical documentation – Annex II & III of the MDR



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HW TD Pitfalls

- Classification: no justification for the full Annex VIII (all chapters and all rules)
- Accessories wrongly classified
- Design and development Information: most of the time too poor (D&D plan; D&D stages; D&D review reports; D&D transfer data and Validation of the production line
- Intended use not the same on each document where it is mentioned
- Not enough justification in GSPR (General Safety and Performance Requirements)
- Clinical Evaluation not compliant – not enough data- literature research not compliant, not reproducible – not considering unfavorable data,…
- PMS/Vigilance not compliant timely wise or under estimation of the risk
- Economic operators: QA Agreements
- PMCF cannot be ignored! At least justification for not having MUST be written.

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SW TD Pitfalls

Same as those for HW +

If the SW is working in combination with HW : good definition of respective roles is key!

- Who is MD: HW/SW or both?
- Who is accessory: HW/SW or both?
- Is the HW a general consumer product without any medical intended use?

Missing some validation between SW and HW especially when it is wearable like phones or watches

Interface description is very important

If some part of the SW is not MD – it should be well defined and described in the TD

Do not forget SOUP description if any and how it is integrated.

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And about AI SW?

MDSW are considered as “High- Risk System” by the AI Act

There is the NB guidance which is quite detailed about their expectation ((Guideline for AI for medical products (johner-institute.com))

And from the AI act there are the similar requirements as in MDR:

- Intended purpose
- Risk Management System
- Technical Documentation
- IFU
- QMS
- Conformity Assessment
- Generate Logs to be retained for the “appropriate” timeframe (10 years after the last unit put on the EU Market for MDR.

And the other ones: see next slide

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And about AI SW?

MDSW are considered as “High- Risk System” by the AI Act

New requirements from AI Act:

Data governance

- Training, validation & testing data sets
- Data governance process
- Setting within which the AI system is intended to be used must be taken into account

Record keeping: logging

- Period of each use
- Reference database against which input data has been checked
- Input data for which the search has led to a match
- Identification of the natural persons involved in the verification

Human oversight

- Verification by natural person might be necessary

Accuracy, Robustness and Cybersecurity

Obligation of users

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And about AI Act

There are also some Obligation of Users

- Must follow IFU
- Must ensure input data is relevant in view of the intended purpose of the high-risk AI system
- Obligation to inform the provider and suspend the use of the system when suspecting a risk (Article 65) or identify a serious incident or any malfunctioning (Article 62)
- Need to keep logs if they are under their control
- Obligation to perform a Data protection impact assessment when applicable

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Do not forget

Update of the Quality Management system with the Specifics MDR requirements about it:

- Vigilance
- PRRC
- Regulatory compliance procedure (how to keep the TD up-to-date?)
- EudaMed
- UDI
- PMS/PMCF
- Clinical Evaluation

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Conclusion

To remember

- Strategy
- Planning
- Be precise – follow Requirements
- Make NB life easy
- QMS update

=> applicable for product classification except for the Class I/A product for which there is no NB involved.

Thank you

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