Your Regulatory Partner

MDR and medical device software, January 2020

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sis STANDARD DEVELOPER 2019

SEK SVENSK ELSTANDARD

EAAR European Association of Authorised Representatives

SWEDISH Medtech

QAdvis – Key competence areas

QMS In-the-cloud

Turn Key QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

European Authorised Representation

Providing European representation for non-EU MedTech companies
Active member of EAAR (European Association of Authorized Reps)

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management
And more…

Agile, Lean and Six Sigma

Training and consulting in cooperation with US partner

QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Files
Global Regulatory Support
Vigilance, Recalls, PMS
Clinical Evaluation and Clinical Studies

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Presentation of the trainers - Robert Ginsberg

- 30+ years in SW Development
- 25+ years in Medical Device SW
- Participated in > 20 audits, FDA, MDD, etc.
- Certified Lead auditor (ISO 13485 & QSR)
- Co-author to IEC 62304, 82304-1, 80001-1, 80002-1, 80002-2
- SW Expert EU SW Workgroup & MDCG
- Scrum Master

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Presentation of the speaker - Emma Axelsson

- Senior quality and regulatory consultant for medical devices and in vitro diagnostics
- Quality and Regulatory Manager medical device company
- Quality management system (ISO 13485:2016)
- MDD/MDR and IVDD/IVDR

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Background

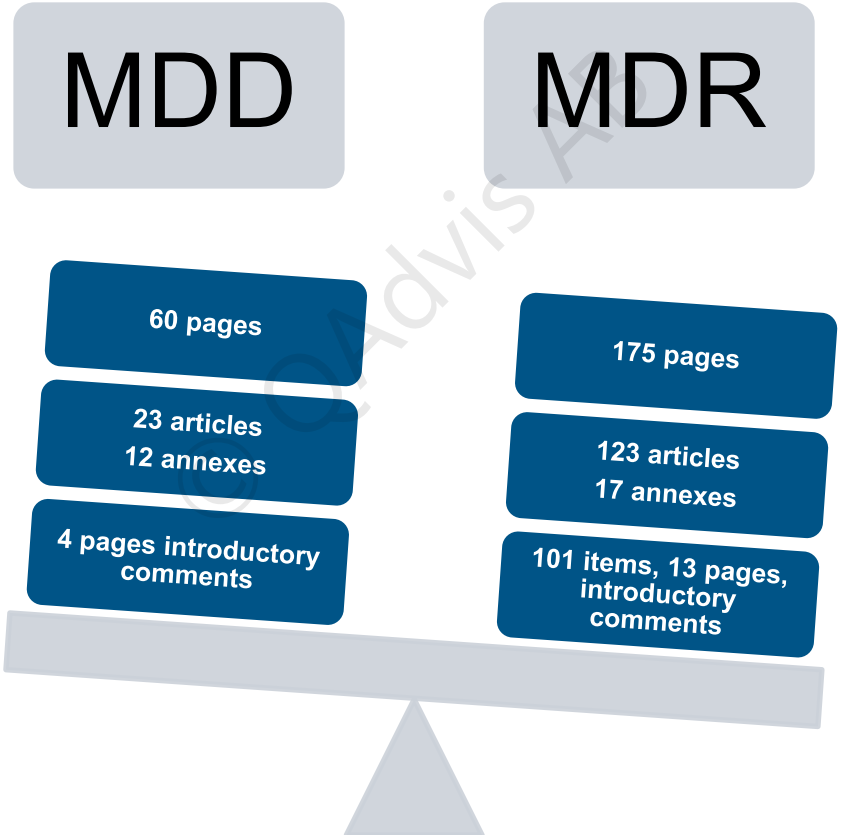
MDR 2017/745

Directives
- AIMDD (90/385/EEG, LVFS 2001:5)
- MDD (93/42/EG, LVFS 2003:11)

IVDR 2017/746

Directive
- IVDD (98/79/EG, LVFS 2001:7)

Overview



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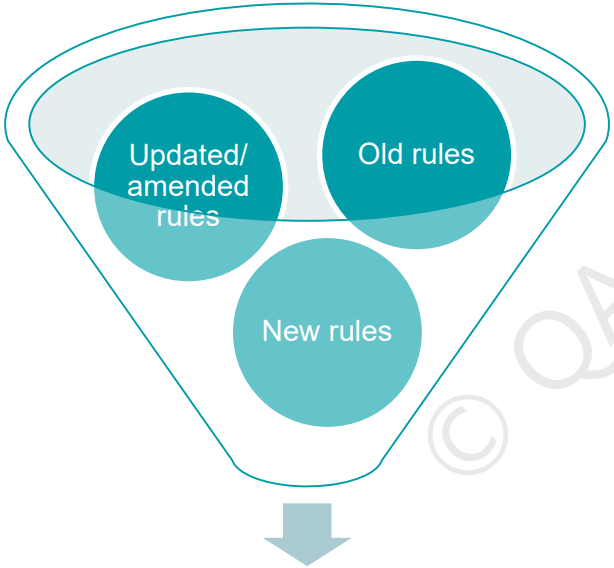
Classification rules news and updates



Classification Rules

(MDR/IVDR Annex VIII)

Many devices will belong to a higher class under MDR/IVDR, leading to stricter requirements and higher level of control by NB.

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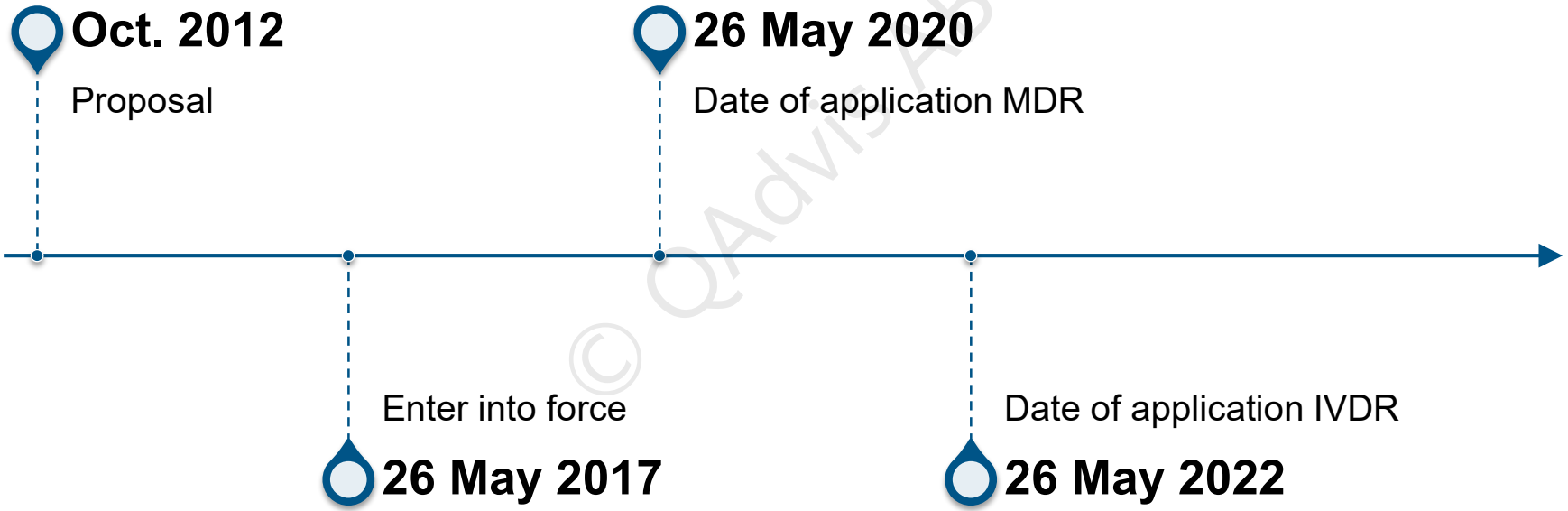
Background - Timeline



(MDR Article 123 / IVDR Article 113)

Economic operator

- Article 10 – General obligations of manufacturers
- Article 11 – Authorized representative
- Article 13 – General obligations of importers
- Article 14 – General obligations of distributors

(MDR/IVDR)

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Person Responsible for Regulatory Compliance (PRRC)

Manufacturer shall have available within their organization at least one person responsible for regulatory compliance.

"The person responsible for regulatory compliance 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."

(MDR/IVDR Article 15)

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Technical Documentation

- Intended purpose (Article 2(12))
- Technical Documentation (Annex II)
- Technical Documentation on PMS (Annex III)
- Declaration of Conformity (Annex IV)
- General Safety and Performance Requirements (Annex I)
- Clinical Evaluation / Performance evaluation (Annex XIV/XIII)

(MDR/IVDR)

General Safety and Performance Requirements (GSPR) – Overview

- Change from MDD Essential Requirements (ER) to General Safety and Performance Requirements (GSPR)
- Checklist recommended
- Reference to method of compliance
- Reference to evidence of compliance

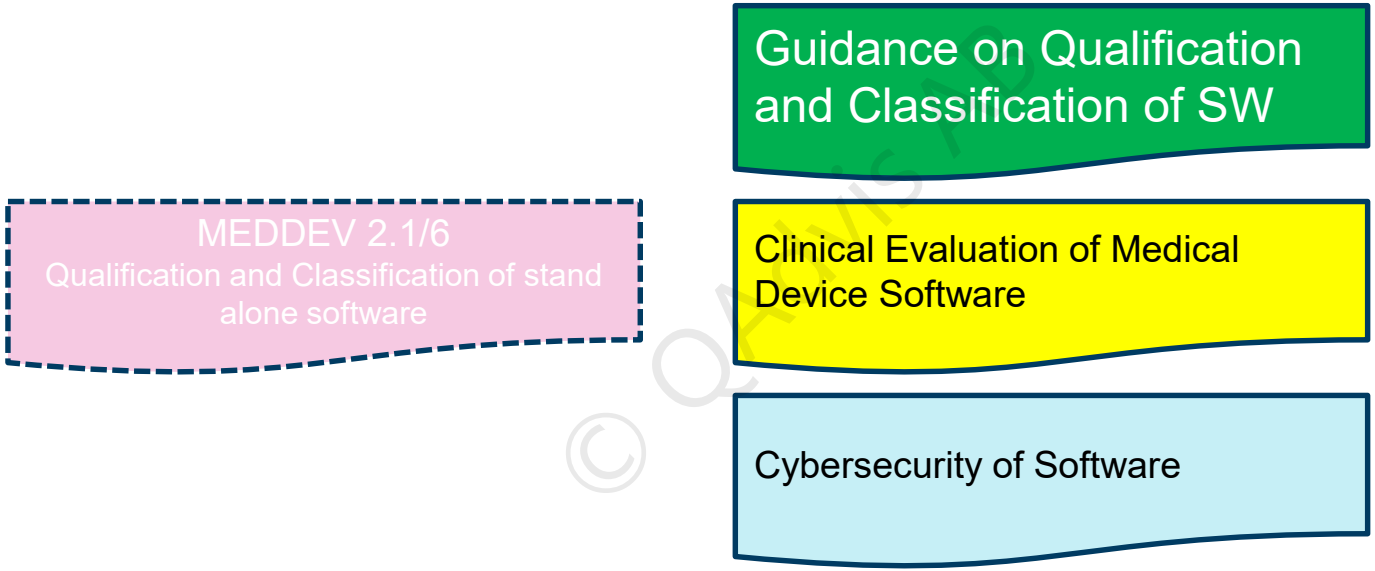
(MDR Annex I)

Intended purpose

- Shall be defined by the manufacturer
- Basis for classification
- The purpose for which a device is intended, according to;
  - Label
  - Instructions for use
  - Promotional or sales materials
  - Statements
  - As specified by the manufacturer in the clinical evaluation

(MDR Article 2 (12))

There are new guidelines to clarify the expectations in MDR and IVDR for software



Released now:

MDCG 2019-11 Guidance on Qualification and Classification of SW in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

MDCG 2019-16 Guidance on Cybersecurity for medical devices

To be released: MDCG 2019-XXX Clinical Evaluation of Medical Device Software

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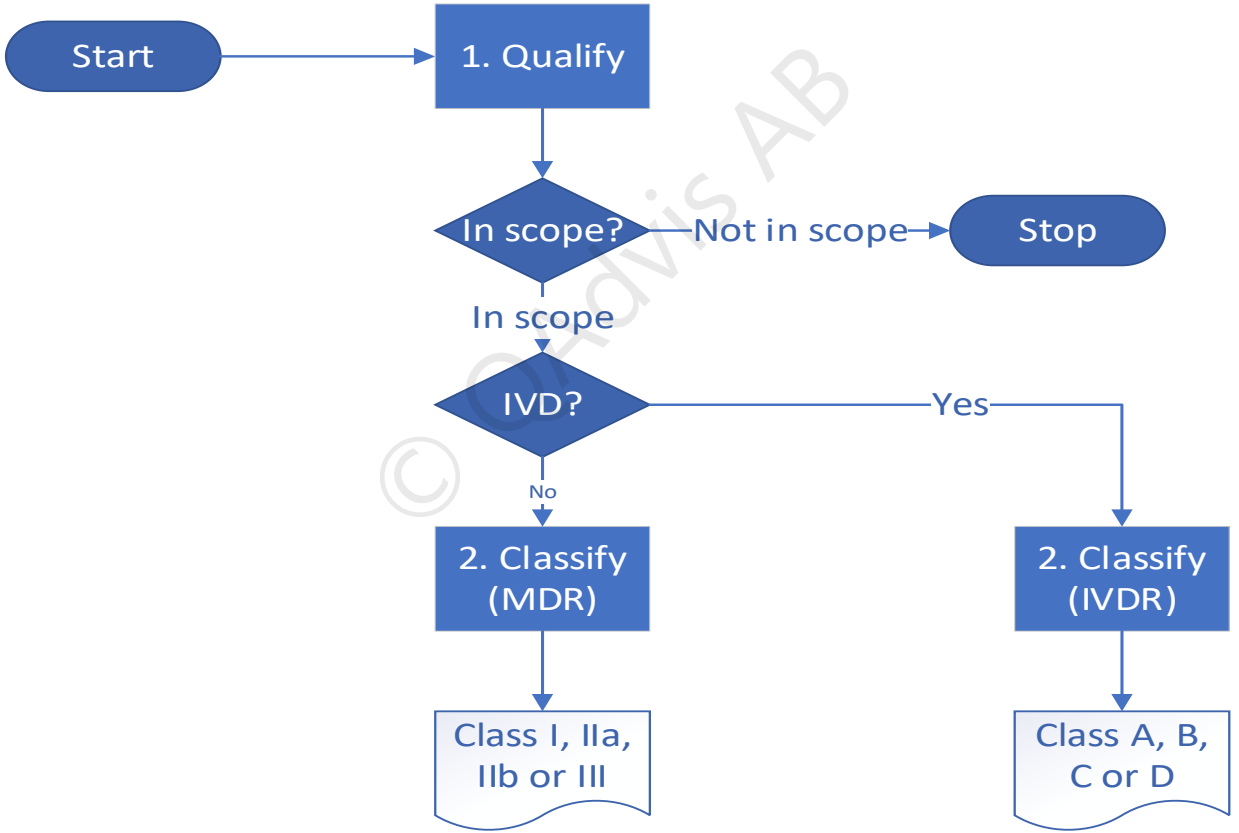
Intended Purpose is crucial for the classification of a MDSW product. What is the class of a device tracking female ovulation?

- Contraception – Class IIb
- Preconception – Class I
- Otherwise – maybe not a medical device at all?

MDSW = Medical Device software

Qualification and classification



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There is a new classification rule in MDR for active therapeutic devices – No. 22

Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III

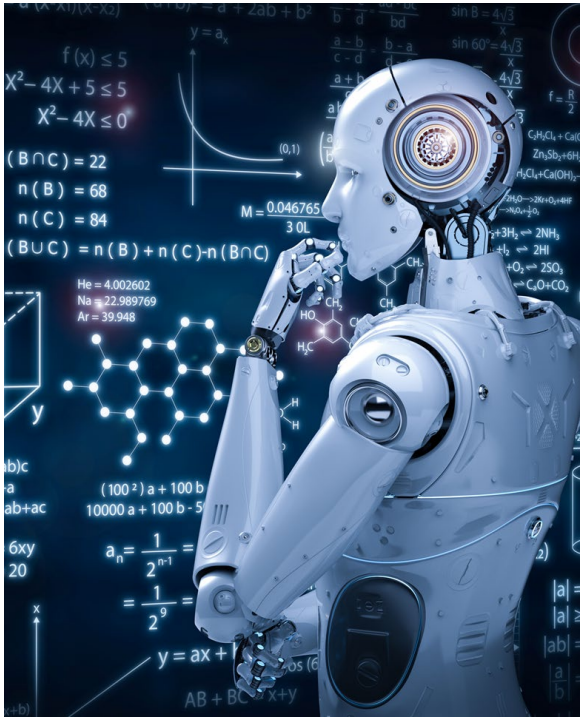
New candidates in addition to external defibrillators

- Systems that control the temperature in baby incubators via skin sensors
- Systems that regulate ultrafiltration in dialysis depending on the patient's blood pressure
- Systems that automatically adjust ventilation patterns to the patient's condition

Source: https://www.tuv-sud.com

There is a new classification rule in MDR for medical device software – rule 11

- Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes - Class IIa
  - May cause death – Class III
  - May cause serious deterioration of state of health or surgical intervention – Class IIb
- Monitoring of physiological processes – Class IIa
- Monitoring of vital physiological parameters, variations of those parameters could result in immediate danger – Class IIb
- All other software – Class I



For complete wording, see Annex VIII of MDR

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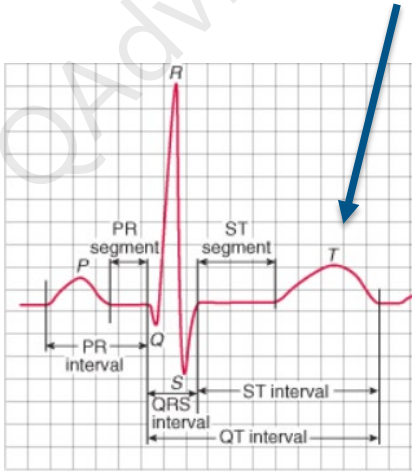
Device hacks - example

MedSec hacks the
Merlin@home Transmitter

Demonstrates with a
pacemaker programmer

Delivers “shock on T”



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GSPR's in the MDR and IVDR are more demanding about cybersecurity

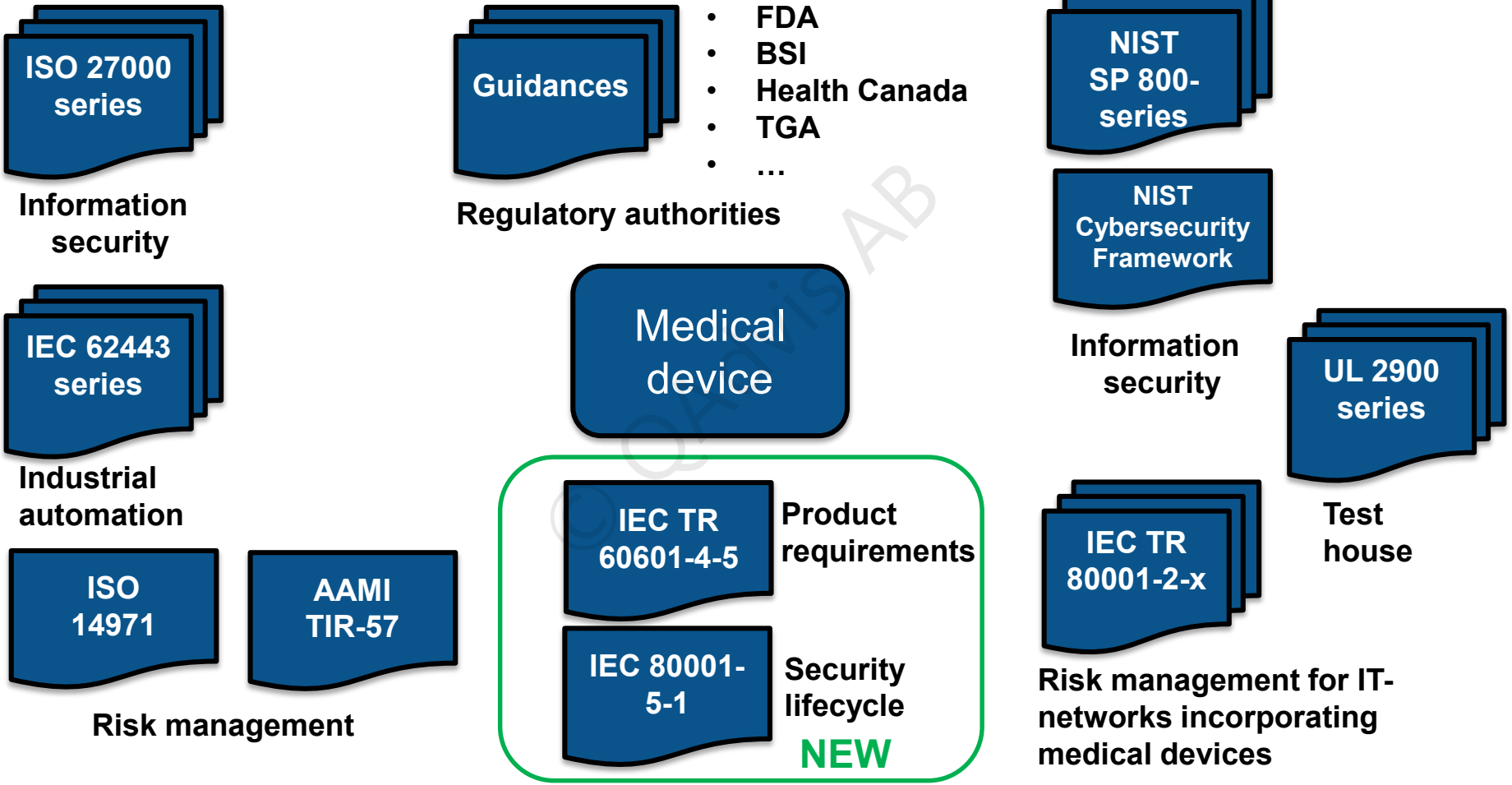
MDR:

17.2: "…state of the art taking into account the principles of development life cycle, risk management, including information security…"

17.4: "Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended."

IVDR:

- Identical requirements as MDR

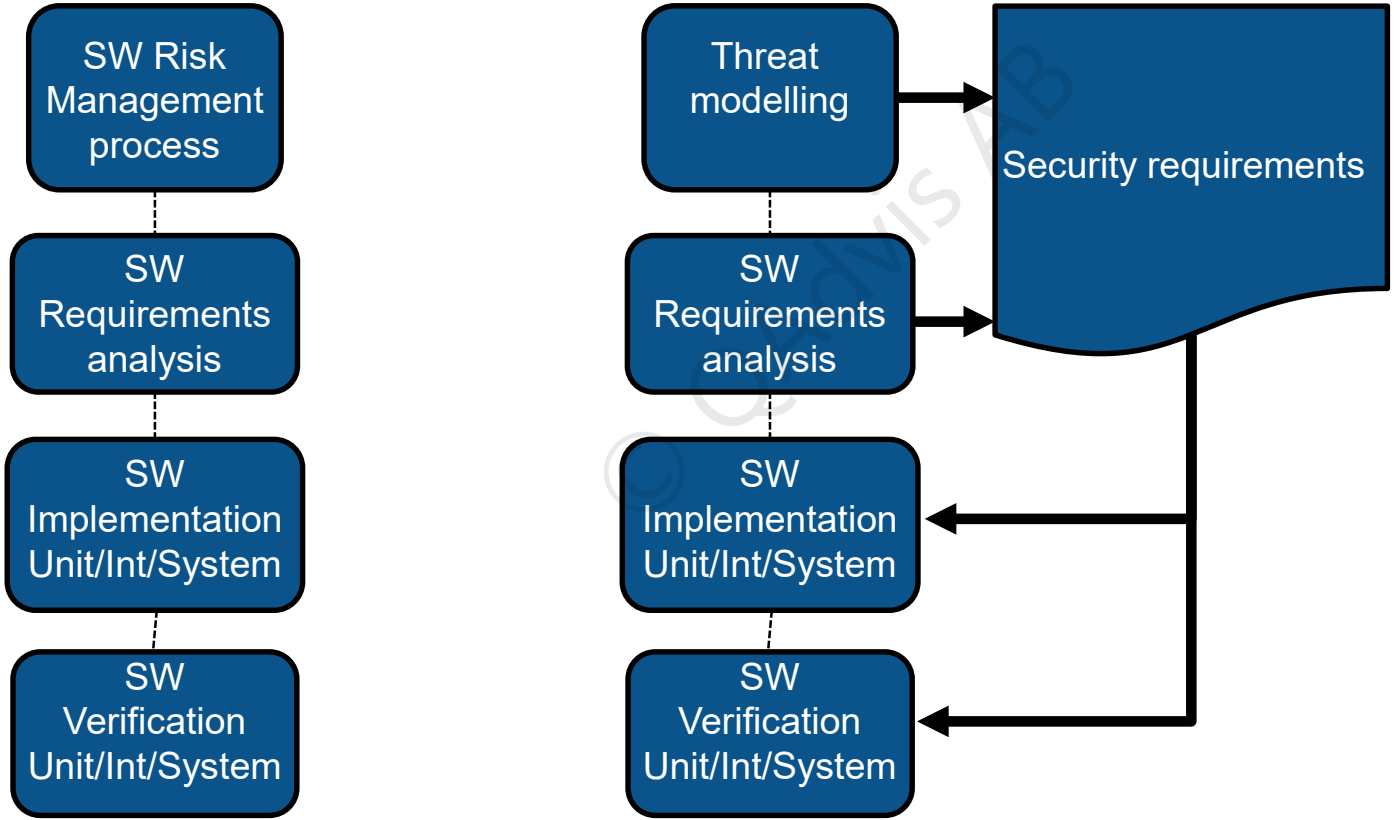

ISO 27000 series
Information security
Guidances
FDA
BSI
Health Canada
TGA
…
Regulatory authorities
NIST SP 800-series
NIST Cybersecurity Framework
Information security
IEC 62443 series
Industrial automation
Medical device
UL 2900 series
Test house
IEC TR 60601-4-5
Product requirements
IEC 80001-5-1
Security lifecycle
NEW
IEC TR 80001-2-x
Risk management for IT-networks incorporating medical devices
ISO 14971
AAMI TIR-57
Risk management

Safety

62304

Security

80001-5-1



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Safety

62304

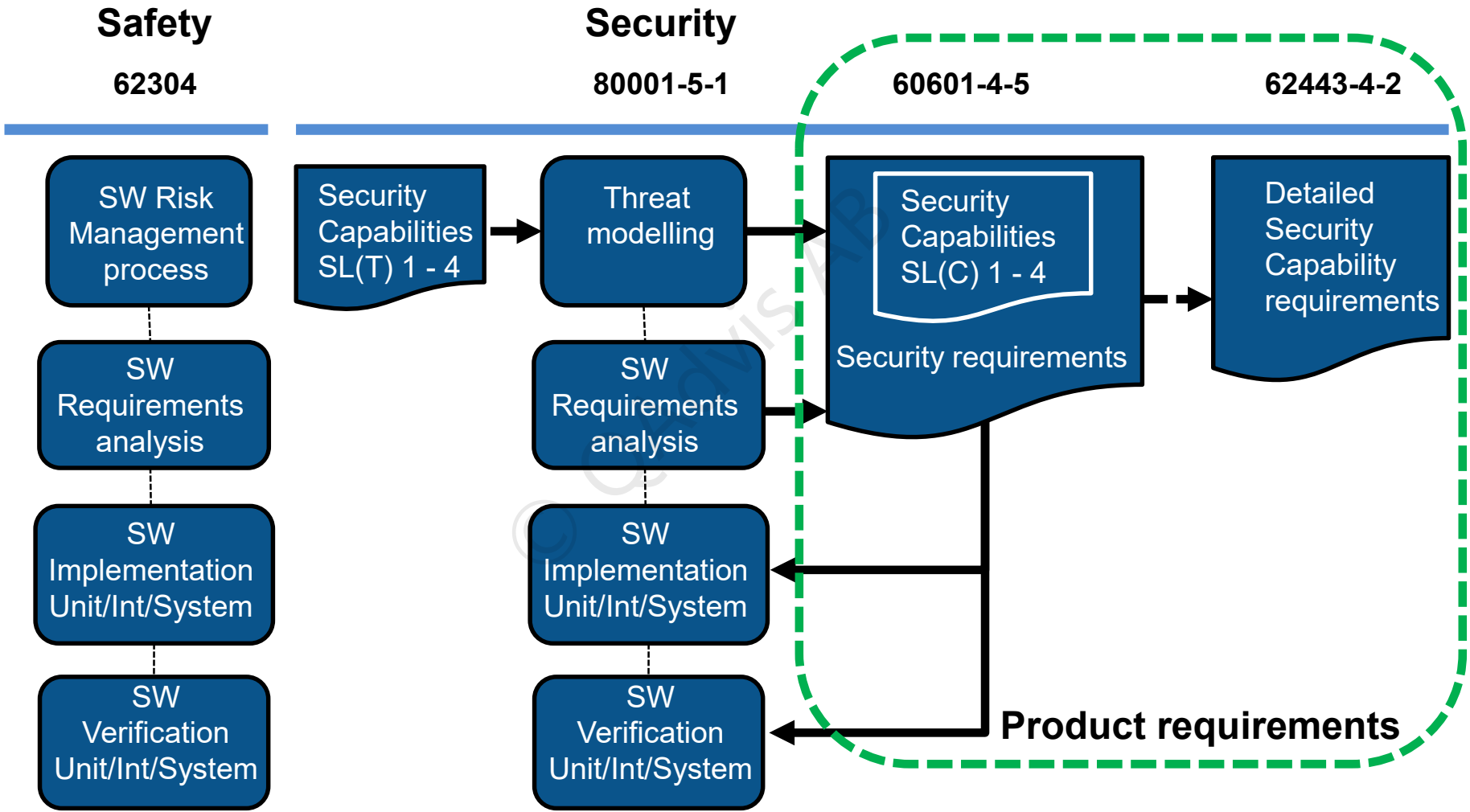
SW Development planning

Security

80001-5-1

SW Development planning

- Development process (=same)
  - Configuration management with change controls and audit logging
- Development environment security
  - Protect the IT infrastructure
  - Protect product SW
- Secure coding standards
  - Avoid exploitable constructs
  - Avoid bannedfunctions and design patterns
  - Use automated tools (static analysis etc)
  - General secure coding practices
  - Validate all inputs that cross trust boundary


Safety
62304
Security
80001-5-1
60601-4-5
62443-4-2
SW Risk Management process
SW Requirements analysis
SW Implementation Unit/Int/System
SW Verification Unit/Int/System
Security Capabilities SL(T) 1 - 4
Threat modelling
SW Requirements analysis
SW Implementation Unit/Int/System
SW Verification Unit/Int/System
Security Capabilities SL(C) 1 - 4
Security requirements
Detailed Security Capability requirements
Product requirements

General Safety and Performance Requirements of MDR will be much more demanding on handling Single Faults

MDD	MDR	
12. Requirements for medical devices connected to or equipped with an energy source	**17. Electronic programmable systems - Devices that incorporate electronic programmable systems and software that are devices in themselves**	
12.1. Devices incorporating electronic programmable systems must be desi... perform... the eve... means ... conseq...	17.1 Devices that incorporate electronic programmable systems, including	Similar
12.1a ... softwar... the sta... develop...		
	features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise).	
	17.4 The manufacturer shall describe minimum requirements on hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.	New requirement

17.1 Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

MDR = Medical Device Regulation, MD SW = Medical Device Software

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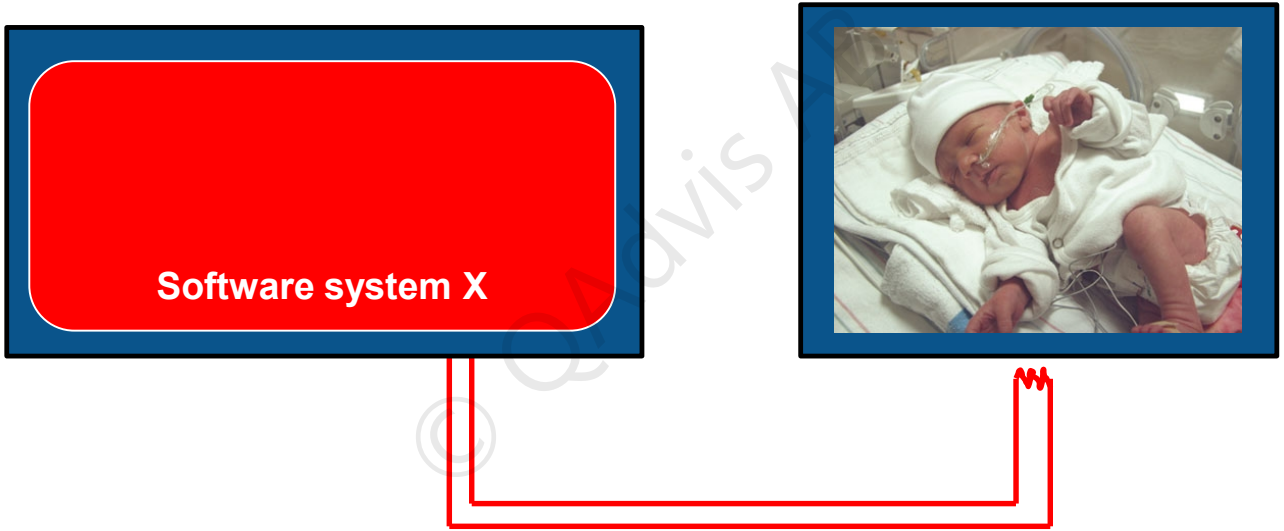
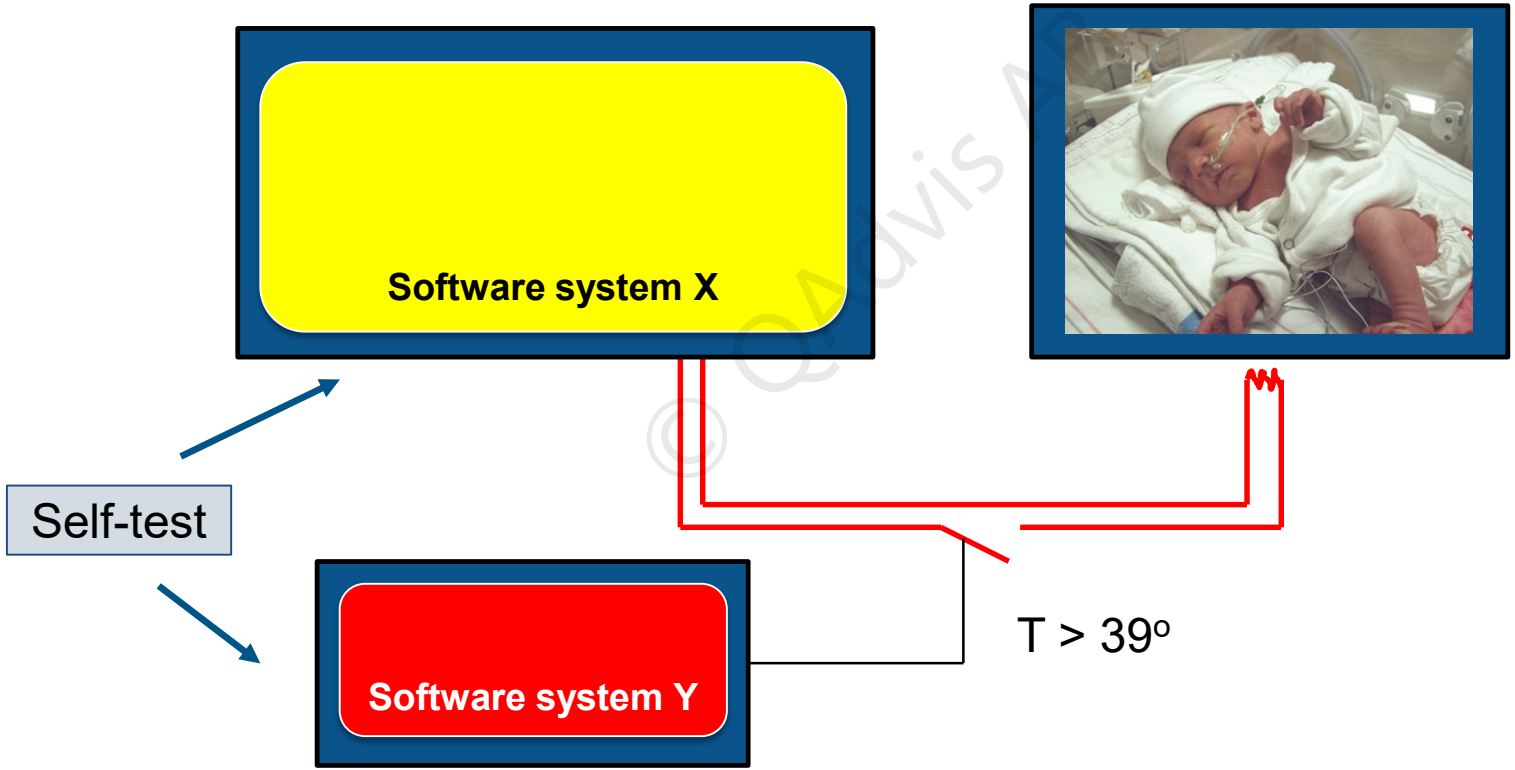
Simple architecture – might be questioned by a Notified Body



The architecture can be modified to improve the chances to have an acceptable architecture



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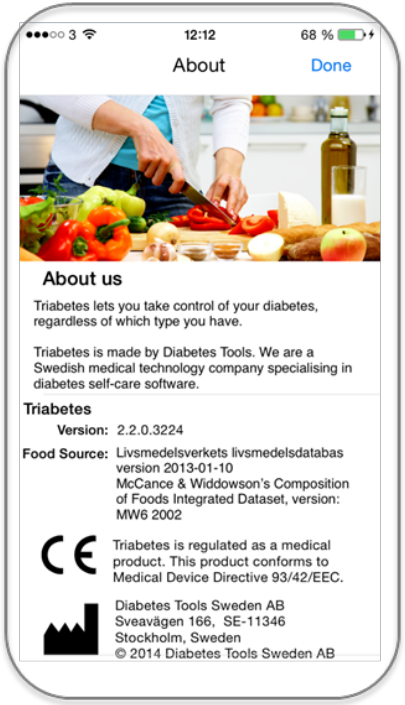
Clinical Evaluation of MDSW according to MDR



- Performed as described in
  - Article 61 General requirements on clinical evaluation
  - Annex XIV Detailed requirements on clinical evaluation and post-market clinical follow-up

- MDR does not distinguish between SW and non-SW devices, that is
  - No exceptions for SW
  - No additional requirements for SW

MDSW = Medical Device software

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Clinical Evaluation of Medical Device software - MDCG Guidance

- Document to be published
  - Based on IMDRF document N41 - *Software as a Medical Device (SaMD): Clinical Evaluation*
  - Adapted to comply with MDR and IVDR
  - Covers all Medical Device software (not only SaMD)

- "Performance evaluation concept"
  - Scientific validity (HbA1c – severity of diabetes)
  - Analytical validation (Technical testing)
  - Clinical validation (Usability, …)

IMDRF = International Medical Device Regulators Forum

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Clinical Evaluation of MDSW – requirements and recommendations

1. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

2. MEDDEV 2.7/1 revision 4 — June 2016 — CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

3. Clinical Evaluation of Medical Device Software - MDCG Guidance

Document to be published

MDSW = Medical Device software, MDCG = Medical Device Coordination Group

Unique Device Identification (UDI)

- Placed on packaging or labels for all devices placed on the market (except custom made devices)
- Used to report serious incidents and field safety corrective actions
- Basic UDI-DI shall be included in the DoC
- Reported in to Eudamed
- UDI database implementing act need to be developed for assignment of responsibility to assign UDIs

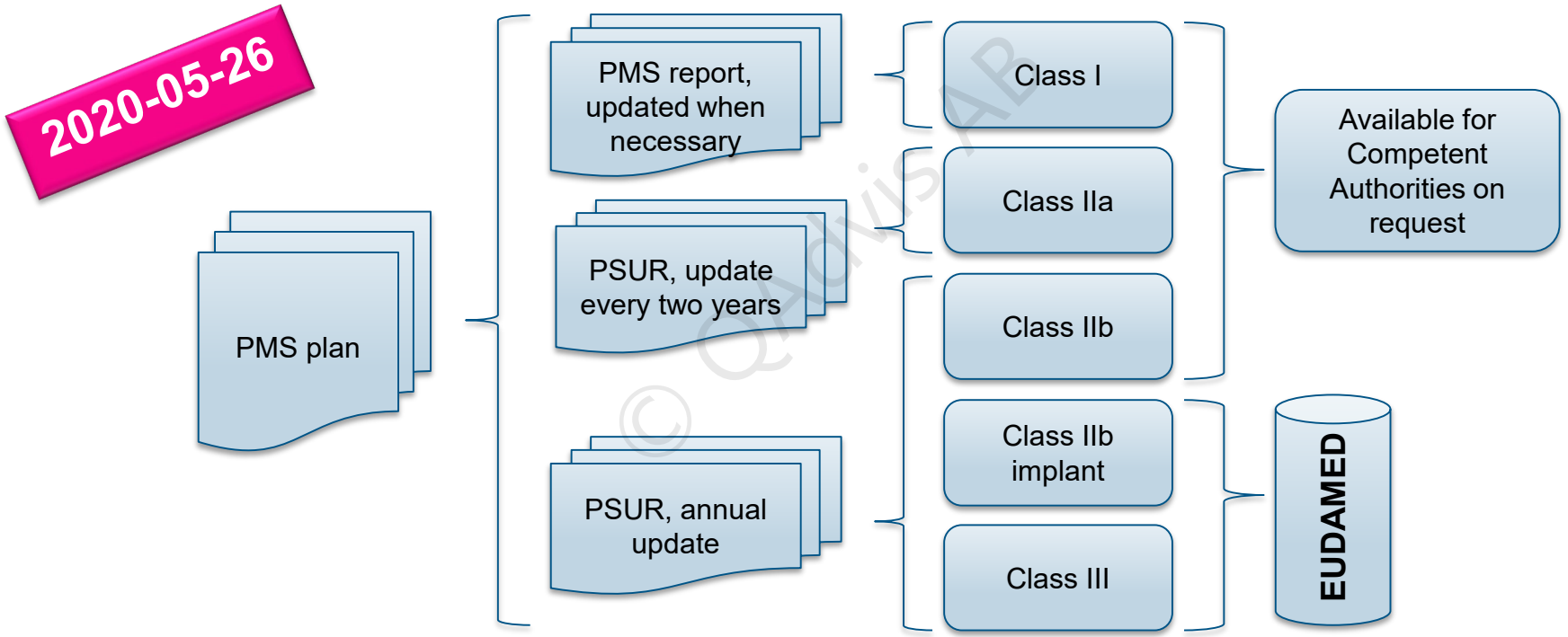
(MDR Article 27 / IVDR Article 24)

Eudamed

- European database for medical devices
- Communication between actors
- Registration of all devices by economic operators
- Accessed by
  - Economic operators
  - Competent Authority
  - Notified Body
  - The general public
- Regularly updated with post-market data and vigilance

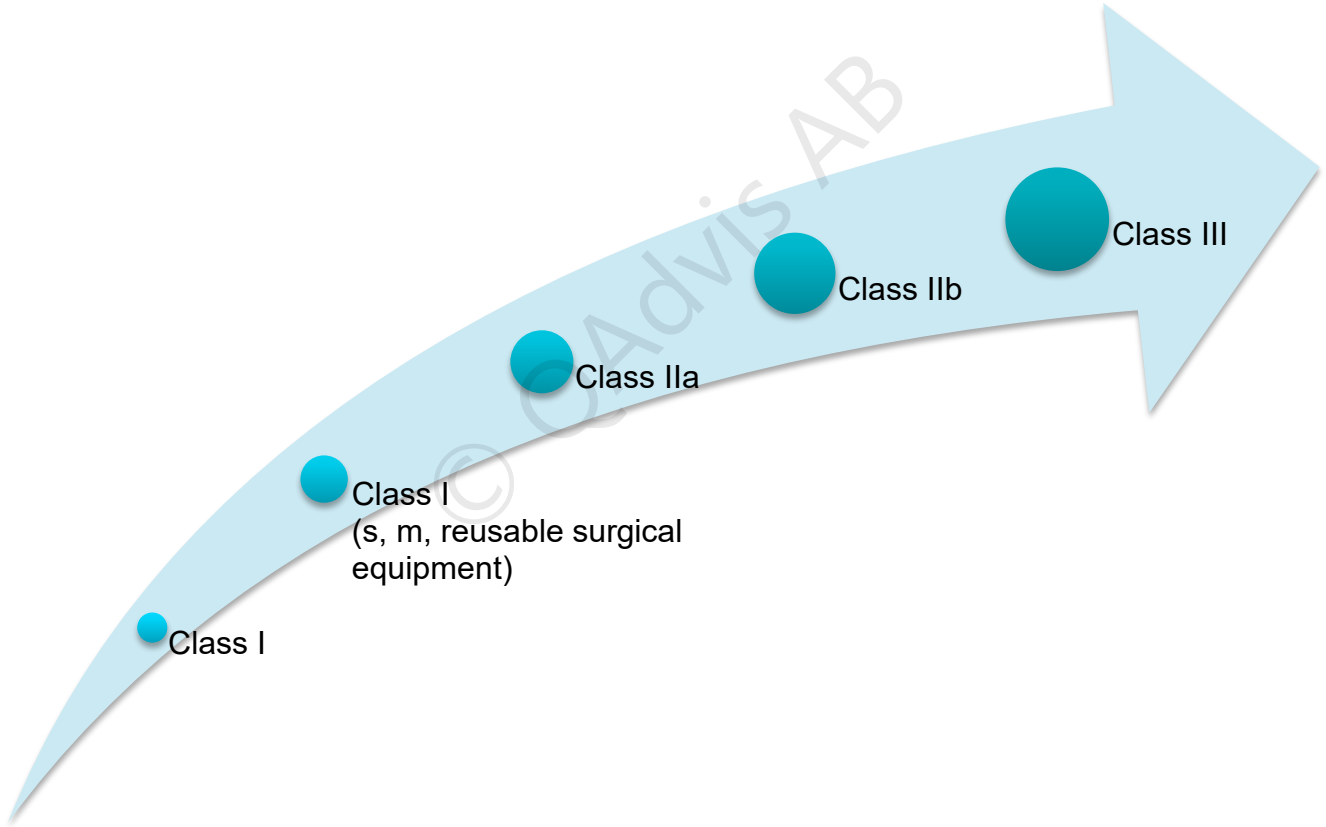
(MDR Article 28 / IVDR Article 25)

Post Market Surveillance (PMS)



(MDR Article 83, 84, 85, 86)

Conformity route – involvement of Notified Body



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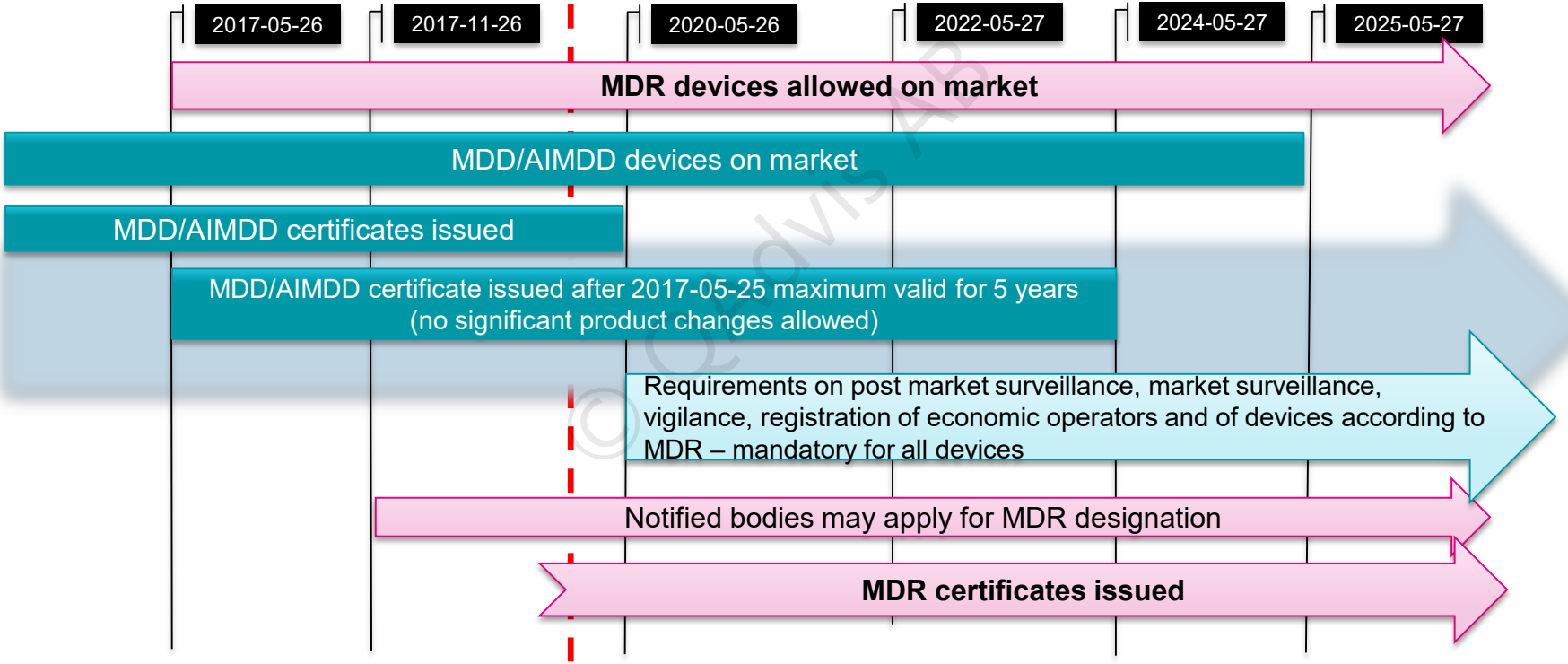
Implementation timeline - MDR



(Article 120/123)

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NB status

- 9 notified bodies designated under MDR
- 3 notified bodies designated under IVDR

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 1912	DARE!! Services B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany

(https://ec.europa.eu/growth/tools-databases/nando/index.cfm)

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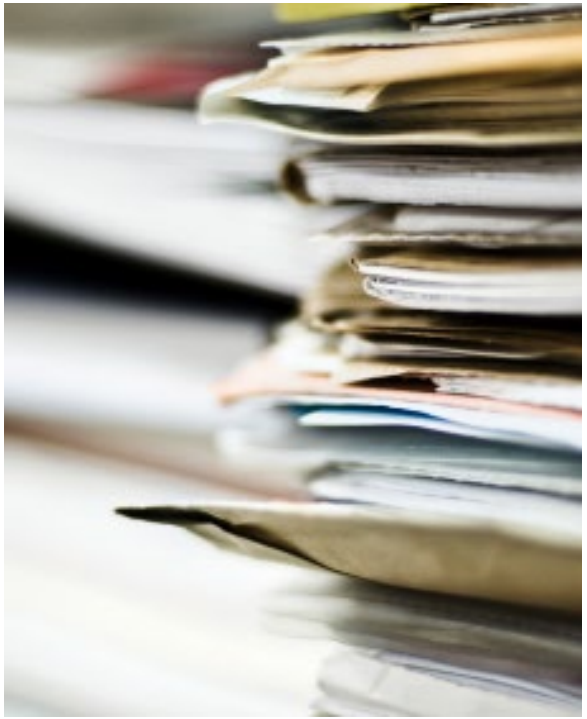
MDCG guidelines

- MDCG 2019-3 Interpretation on article 54(2)b
- MDCG 2019-7 guidance person responsible for regulatory compliance
- MDCG 2019-8 Implant card
- MDCG 2019-9 Summary of safety and clinical performance



(https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en)

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MDCG guidelines

- MDCG 2018/2019 UDI guidance documents
- MDCG 2019-4/5 Eudamed registration
- MDCG 2019-11 Qualification and classification of software
- MDCG 2019-16 Guidance on cybersecurity for medical devices
- MDCG 2019-15 Guidance notes for class I medical device

(https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en)

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Corrigendum MDR and IVDR

- Editorial corrections
- Class I MDD devices that are up-classified

Corrigendum to Regulation (EU) *2017/745* of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017)
ST/13081/2019/INIT

OJ L 334, 27.12.2019, p. 165–166 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)

CELEX number: 32017R0745R(02)

Author: European Parliament, Council of the European Union

Date of document: 27/12/2019; Date of publication

Corrigendum to Regulation (EU) *2017/745* of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017)
ST/15409/2018/REV/1

OJ L 117, 3.5.2019, p. 9–10 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)

CELEX number: 32017R0745R(01)

Author: European Parliament, Council of the European Union

Date of document: 03/05/2019; Date of publication

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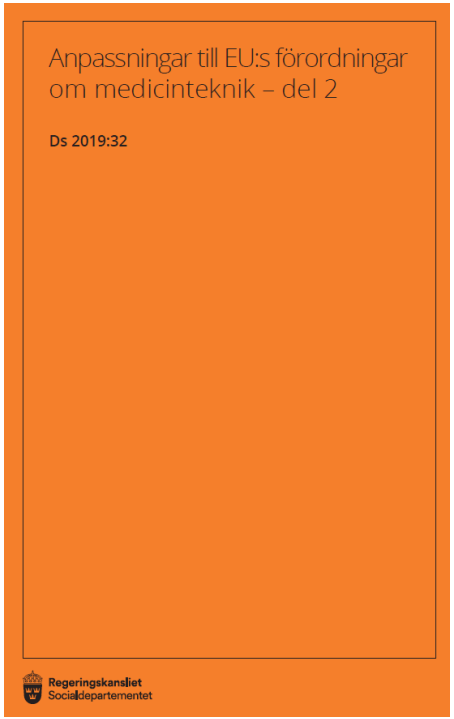
Ds 2019:32



- Language requirements
- National registration
- Fees
- Sanctions and penalties
- Clinical trials
- Market surveillance

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Concerns

- Only 4 month left!
- A lot of work for Notified Bodies and Competent Authorities
- Decreasing number of Notified Bodies
- More devices and manufacturers in need of a Notified Body
- Common Specifications necessary for implementation not published in time
- Necessary Implementing Acts not ready in time

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Conclusions

- Don’t wait for clarifications – act now – the clock is ticking!
- Regular control of published documents
- Close contact with your notified body
- Make a migration plan, get management buy in, secure resources and budget
- Assess your qualification and classification
- Stand in line for a NB – if needed
- Stricter requirements on all players (Authorities, Notified Bodies and Manufacturers)

Thank you for your attention!
Questions & Answers

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QAdvis services

- MDR / IVDR transition support
- CE marking support
- Quality Management System
- Technical Documentation
- Risk Management
- Clinical Evaluation
- Software validation
- Training, see our webpage for more info

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