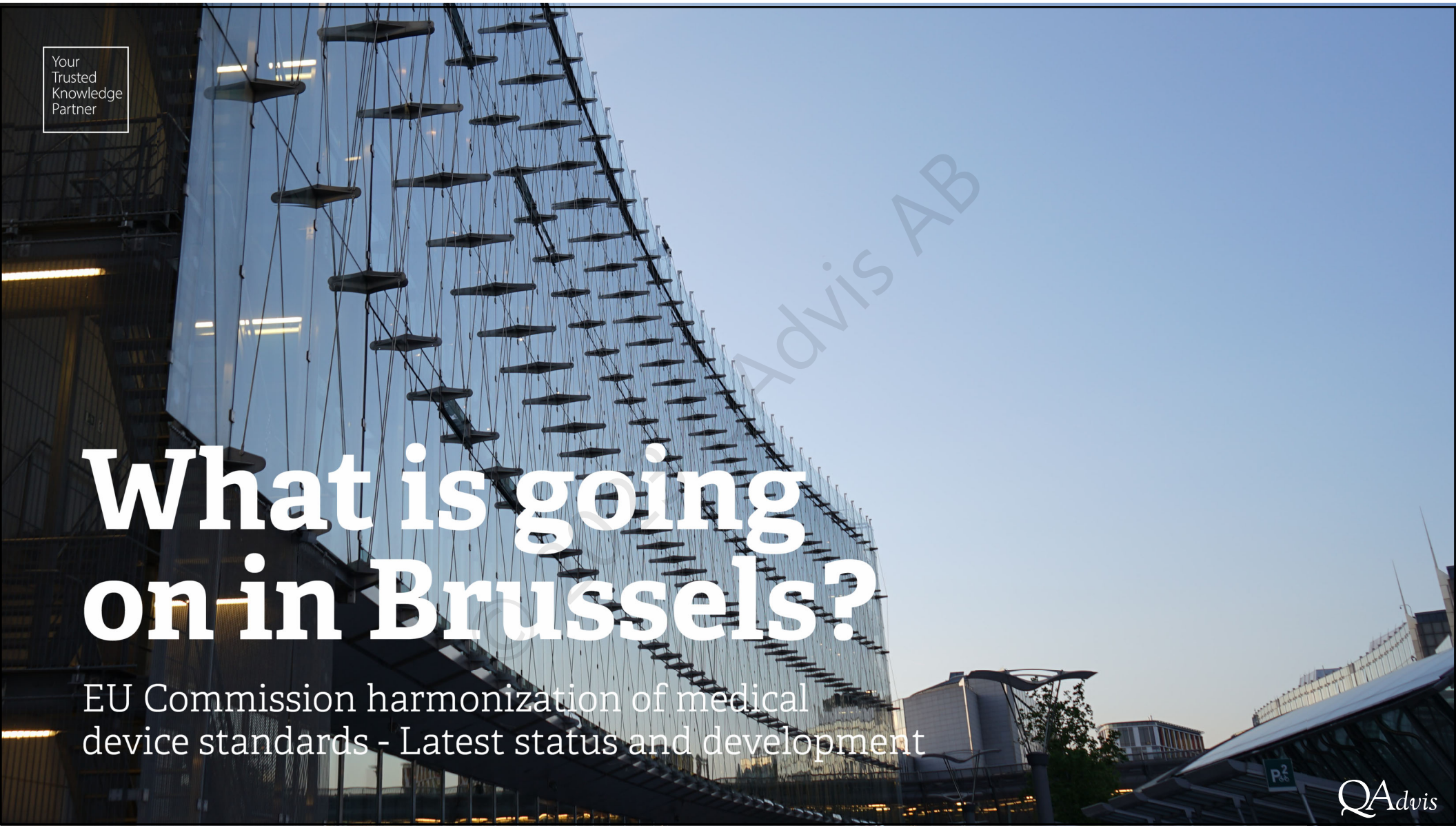
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What is going on in Brussels?
EU Commission harmonization of medical device standards - Latest status and development
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Medical device standards and EU harmonisation progress

2023-02-16

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Disclaimer

Please note that, any views given by us on the interpretation of the legislation represent our best judgement at the time, based on the information available. Such views are not meant to be a definitive statement of law, which may only be given by the Courts.

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Agenda

- Background – benefit of harmonised standards
- Definitions
- Current status on harmonisation process related to MDR and IVDR
- Harmonisation process dynamics
- MDCG work status

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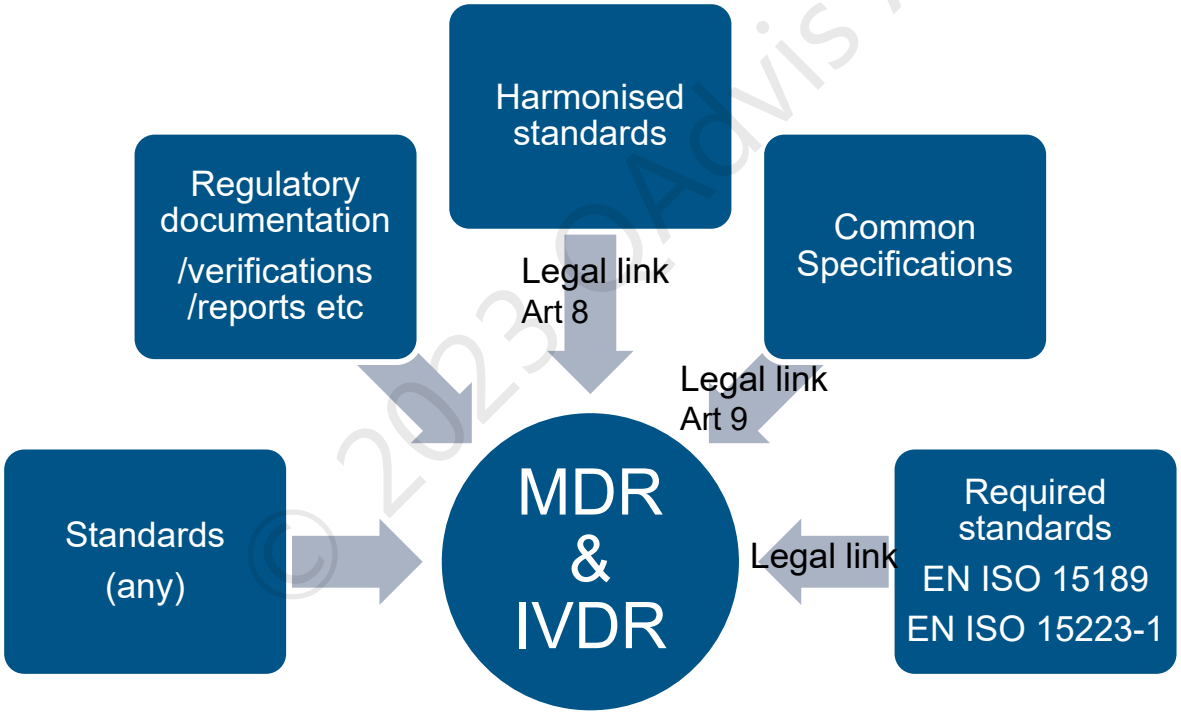
Background



Standardisation Regulation (EU) 1025/2012

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Definition

Definitions MDR Art 2 (70) IVDR (73)

- "harmonised standard" means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012 (European standardisation)

=> i.e. adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation.

Use of harmonised standards

Art (8) MDR, IVDR

- Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

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Definition

Definitions MDR Art 2 (71) IVDR (74)

- "'common specifications' (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.

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Common specifications

Article (9) MDR, IVDR

- "…where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III,…
- "Manufacturers shall comply with the CS …

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Harmonised standards

Useful webpages:

https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en

https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/medical-devices_en

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European standardisation organisations

- European Committee for Standardization (CEN)
- European Committee for Electrotechnical Standardization (CENELEC)
- (ETSI – European Telecommunications Standards Institute)

- Private international non-profit organizations

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Harmonisation process MDR and IVDR

EUROPEAN
COMMISSION

M/575

Brussels, 14.4.2021
C(2021) 2406 final

COMMISSION IMPLEMENTING DECISION

of 14.4.2021

on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council

Standardisation request (SReq).

Will be amended and updated over time

Harmonisation process MDR and IVDR

- Delayed initial Standardisation Request, Impl Decision
  - COM ImplDec. in April 2021, (just before DoA for MDR)
- 1st amendment of SReq, was adopted by 31 Jan 2023
  - CEN/Cenelec will have 1 month to accept
  - MDR 11 new, 5 removed - IVDR 4 new
- 2nd amendment under preparation, likely end 2023
  - Extension of timelines, (27 May 2024 not realistic anymore)

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Harmonisation process MDR and IVDR

Example of some standards in the SReq M/575 + adopted 1st amendment (to be)

- IEC 81001-5-1
  - Health software and health IT systems safety, effectiveness and security - Part 5-1: Security Activities in the product life cycle
- EN 82304-1:2017
  - Health Software - Part 1: General requirements for product safety
- EN 62304:2006+A1:2015
  - Medical device software - Software life-cycle
- EN 62366-1:2015+AC:2015+AC:2016+A1:2020
  - Medical devices - Application of usability engineering to medical devices

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Harmonisation process MDR and IVDR

EUROPEAN
COMMISSION

M/575

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- Initial Standardisation request M/575

Deadline for adoption of the standards: 27 May 2024 - To be revised

	Revision of existing harmonised standards		Draft new harmonised standards
MDR	201	+	27
IVDR	46	+	3

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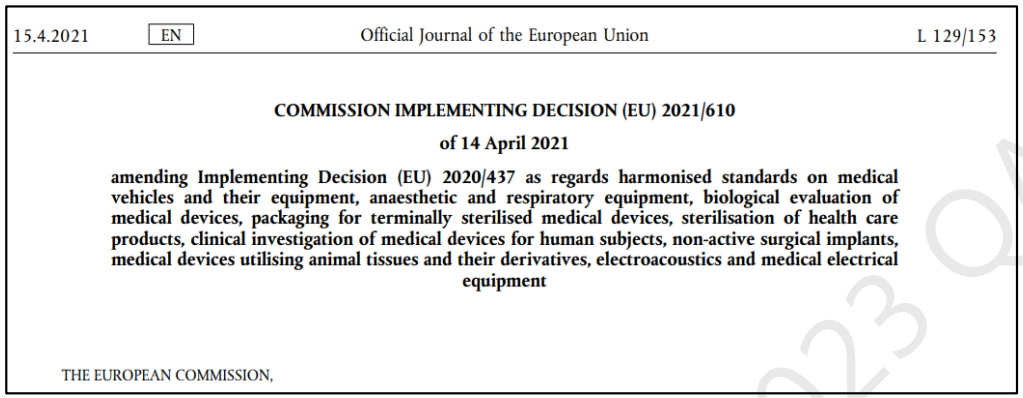
Harmonisation process - old Directives



15.4.2021 EN Official Journal of the European Union L 129/153

COMMISSION IMPLEMENTING DECISION (EU) 2021/610

of 14 April 2021

amending Implementing Decision (EU) 2020/437 as regards harmonised standards on medical vehicles and their equipment, anaesthetic and respiratory equipment, biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products, clinical investigation of medical devices for human subjects, non-active surgical implants, medical devices utilising animal tissues and their derivatives, electroacoustics and medical electrical equipment

THE EUROPEAN COMMISSION,

- Final publication in 21 April 2021 of harmonised standards for the Directives
- Valid until 26 May 2024 to support the transition period, art 120 & art 110. To be revised?

	Harmonised standards
AIMD	47
MDD	268
IVDD	43

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Harmonisation process MDR and IVDR

3 batches of harmonised standards have been published (referenced in OJEU)

- *1st publication:* Commission Implementing Decision, MDR (EU) 2021/1182, of 16 July 2021
  - 6 MDR and 4 IVDR
- *2nd publication:* Commission Implementing Decision, MDR (EU) 2022/6, of 4 January 2022
  - 8 MDR and 5 IVDR

  Including: EN ISO 13485:2016 (QMS) and EN ISO 15223-1:2021 (Symbols)
- *3rd publication:* Commission Implementing Decision, MDR (EU) 2022/757, of 11 May 2022
  - 2 MDR and 1 IVDR

  Including: EN ISO 14971:2019 (Risk Management)

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Harmonisation process MDR and IVDR

In total: 16 for MDR and 10 for IVDR

➡ 200+ to go!

For 2023, two batches are planned in spring and autumn

Likely to increase with more batches per year

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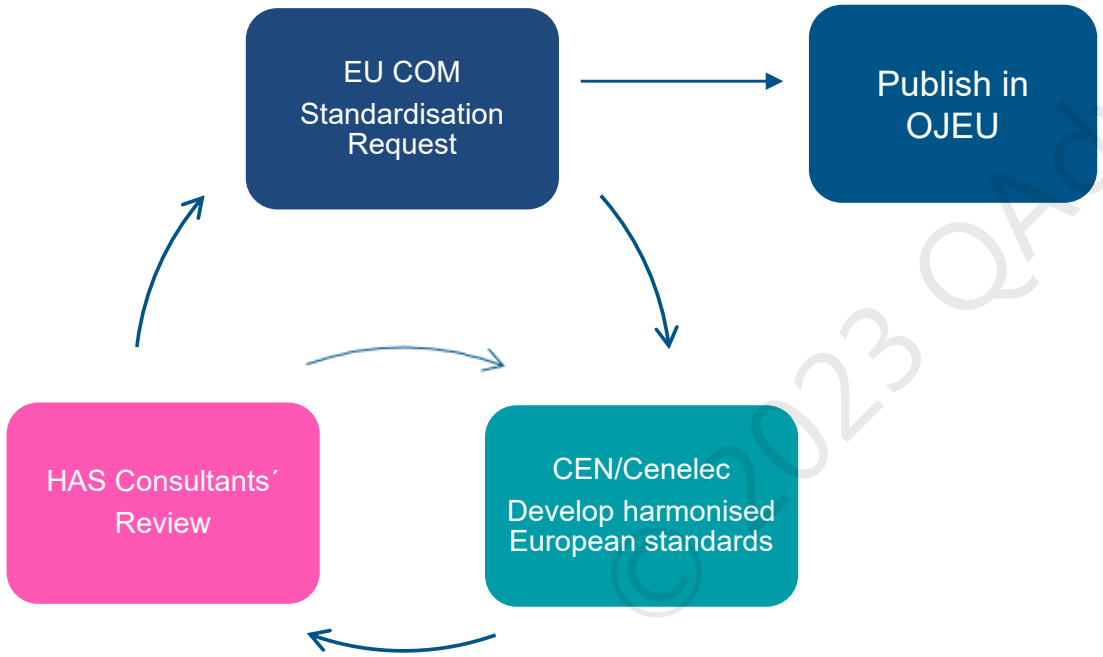
Harmonised standards – simplified process



Slow start – but an improving process

- Rejected initial SReq
- HAS consultant capacity was limited in 2022
- Initial different views CEN/Cenelec v.s. HAS

➢ Improved communication, dialogue, understanding

➢ Secured HAS funding

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Harmonised standards

European Foreword

EN Standard

Z Annexes

Example: EN ISO 13485:2016/A11:2021

Table ZA.1 — – Correspondence between this European standard and the requirements of Article 10 of Regulation (EU) 2017/745 [OJ L 117]

Requirements of Article 10 of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	4.1, 7.1, 7.2.1 c), 7.2.2 c), 7.3, 7.5	Partially covered. EN ISO 13485 includes requirements for the QMS, design and development and manufacturing that require incorporation of the regulatory requirements into the quality management system.
2	7.1	Partially covered. EN ISO 13485 includes requirements to risk management in product realization. The detail of the specific requirements of Annex 1, Chapter 1 of the Regulation is not stated explicitly.
3		Not covered. 7.3.7 of EN ISO 13485 requires clinical evaluation in accordance with applicable regulatory requirements. The details contained in Article 61 or Annex XIV are not provided.

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Medical Device Coordination Group (MDCG)

- In total 13 MDCG working groups
  - MDCG Standards is a new working group. Well needed. Very transparent and open communication.

- MDCG 2021-5 *Guidance on standardisation for medical devices*
  - published in April 2021
  - general information on harmonisation, presumption of conformity, concept of voluntary use of standards, state of the art

- The revised “Blue guide”, section 4.1.2 includes additional contents on standards and harmonisation process.

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Medical Device Coordination Group (MDCG) - Standards

Work programme 2023 for MDCG Standards Group

- 1 Standardisation request – amendments
- 2 Harmonised standards - publish references in OJEU
- 3 Revision of Guidance MDCG 2021-05

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Medical Device Coordination Group (MDCG) - Standards

- Revision of Guidance
  - Task force #1, Standardisation guidance update
    1. Elaborate on the concept of state-of-the-art
    2. Elaborate on consequences of ECJ rulings

COURT OF JUSTICE
OF THE EUROPEAN UNION

  - Task force #2, Cookbook for standards, was ready in Nov 2022
    1. Today targeting TC62, possibly to be extended in scope, and other TCs

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MDCG Standards

MDCG Standards - Task Force #2

- Cenelec TC62 produced a Cookbook – "How to write European harmonised standards"
- Cenelec TC62 and EU COM agreed on critical areas for a smooth HAS consultant assessment

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MDCG standards

Some areas covered in the Cookbook:

- International standards often have a broader scope
  - Clarify in Foreword and Z Annex relevant parts for application under MDR & IVDR
- Definitions of terms – EN Standard v.s. MDR &IVDR
  - Clarify in Foreword and Z Annex how rules for different terms shall be applied

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Common specifications (CS)

- CS published in August 2020 for reprocessing of single use devices
- CS for MDR Annex XVI products
- CS for certain class D in vitro diagnostic devices
- CS for other IVDR, virus related products, are under preparation

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References

- EU COM webpages on Harmonised standards
  - https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en
  - https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/medical-devices_en
- The Blue guide, on implementation of EU products rules
  - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2022.247.01.0001.01.ENG&toc=OJ%3AC%3A2022%3A247%3ATOC
- MDCG 2021-5 Guidance on standardisation for medical devices
  - https://health.ec.europa.eu/system/files/2021-04/md_mdcg_2021_5_en_0.pdf

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Thank you for your attention!

¿ Questions ?

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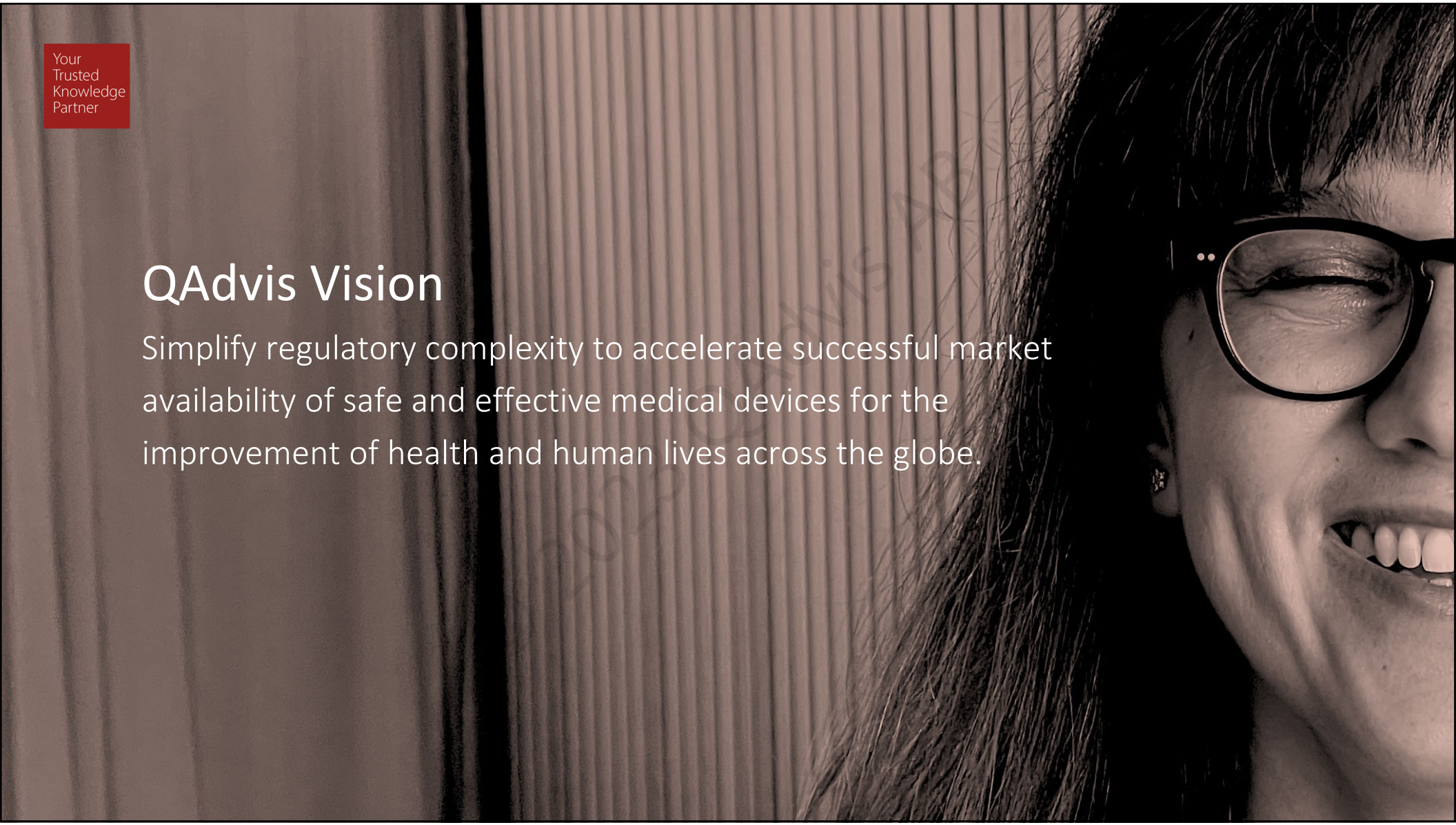
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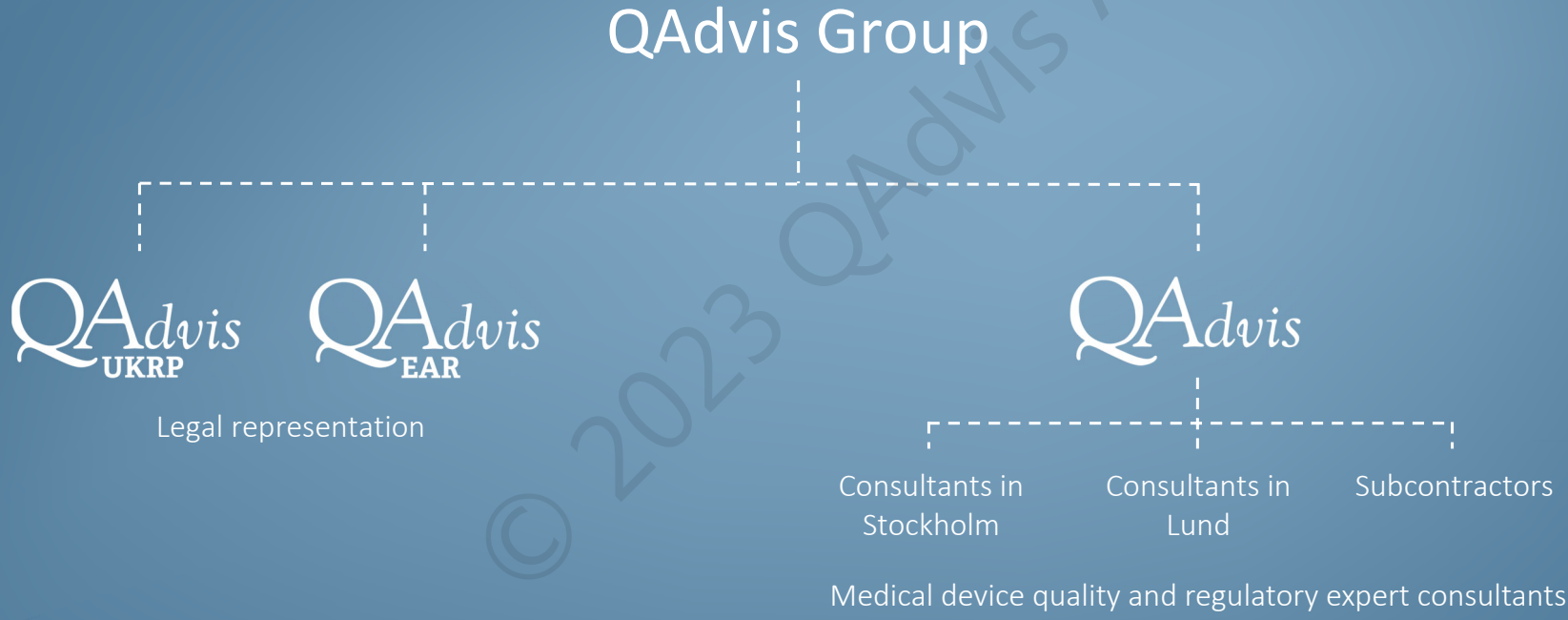
QAdvis Vision
Simplify regulatory complexity to accelerate successful market availability of safe and effective medical devices for the improvement of health and human lives across the globe.

Organisation



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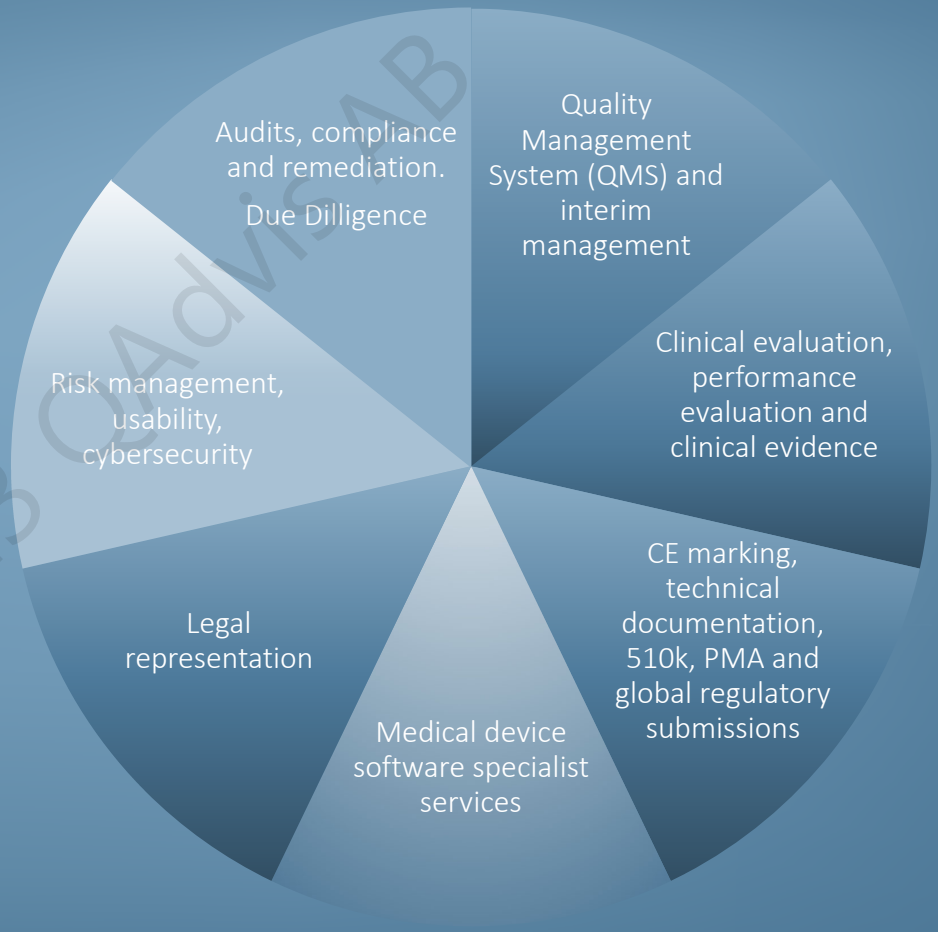
Our services within quality, regulatory and clinical evidence

Your medtech innovations - domestic and international markets.



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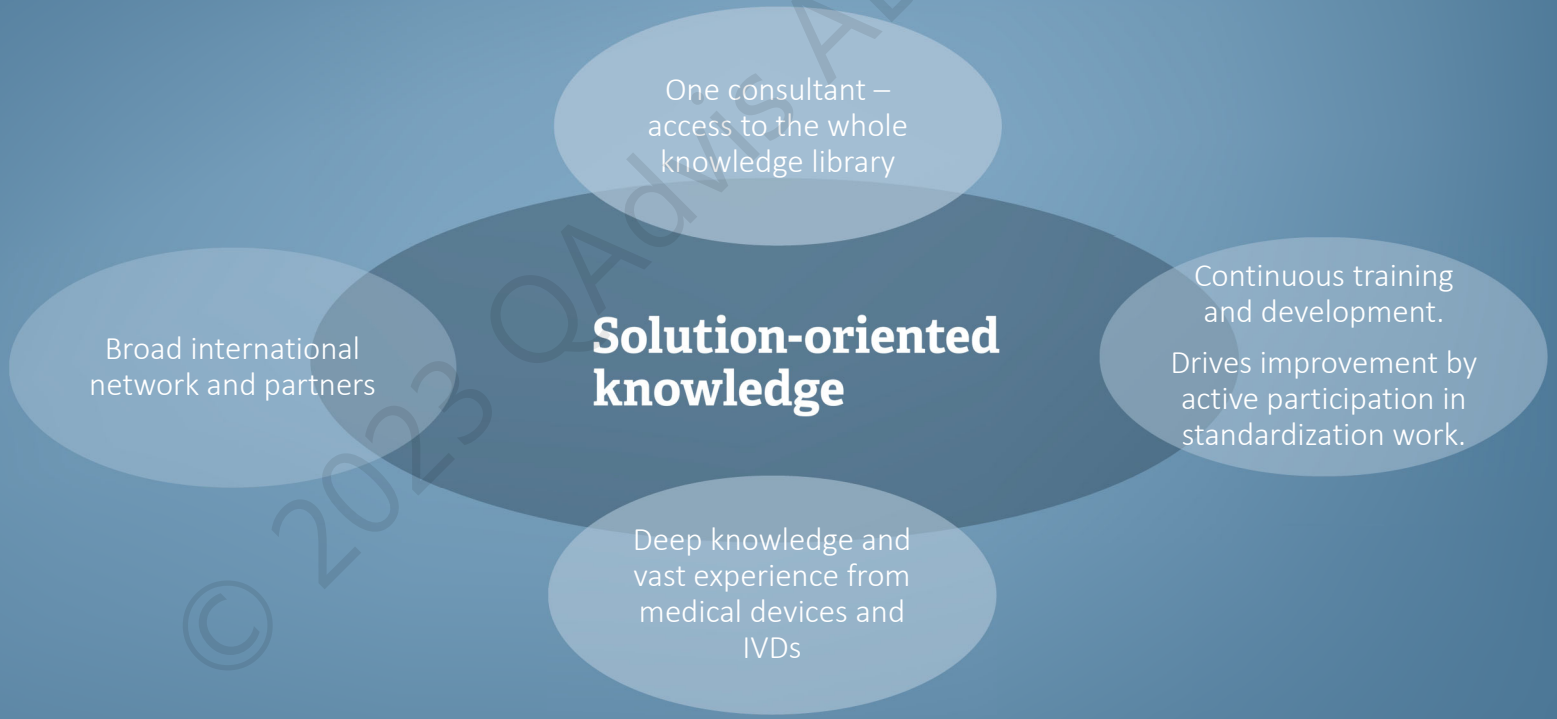
Our strategy to success



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Partners and associations

Partners

aligned elements

IDEON SCIENCE PARK

MEDICON VILLAGE

Oriel STAT A MATRIX

Industry organisations

IEC International Electrotechnical Commission

SIS Svenska Institutet för Standarder

EAAR European Association of Authorised Representatives

SWEDISH Medtech

SWEDISH LABTECH

UKRPA UK Responsible Person Association

EU Projects

TIES TEST

QAdvis Academy

Open and company specific training courses:

- CE-marking
- Risk management for medical devices
- Usability according to IEC 62366-1
- Technical Documentation for medical devices
- Clinical evaluation/clinical performance evaluation
- Cybersecurity for medical devices
- ISO 13485:2016
- EU In-Vitro Diagnostic Regulation (IVDR)
- EU Medical Device Regulation (MDR)
- Good Manufacturing Practice for Medical Devices and IVD devices
- Internal audits based on ISO 13485
- Medical device software process design based on IEC 62304

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