MDR/IVDR Implementation

By Adnan Ashfaq (Pharmi-Med Ltd.)

Pharmi **Med** Ltd

About me and Pharmi-Med Ltd.

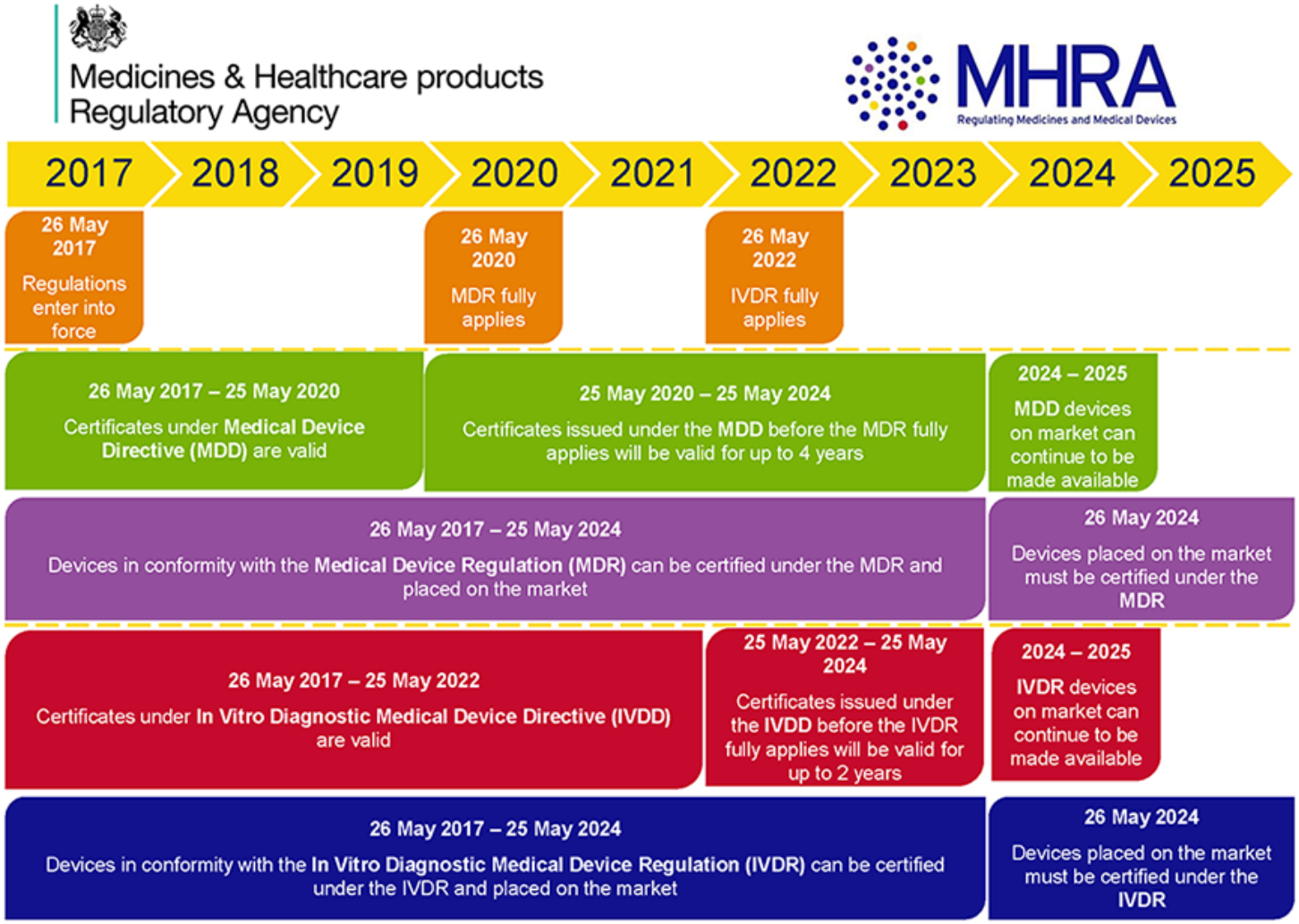
- Adnan Ashfaq (B.Eng, Hons Manufacturing Systems Engineer)
- Working in Medical Device and Pharmaceutical Industries for 20 years.
- Started up in Validations - 1999 and moved over to Quality/ Regulatory in 2006.
- Set up Pharmi-Med Ltd in October 2011 to apply industry knowledge to manufacturers.
- Worked in Class I, IIa/IIb, III, IVD Class – Self Testing
- Interested in all regulatory changes which impact Medical Device manufacturers

Part One – The Regulations

Short Video

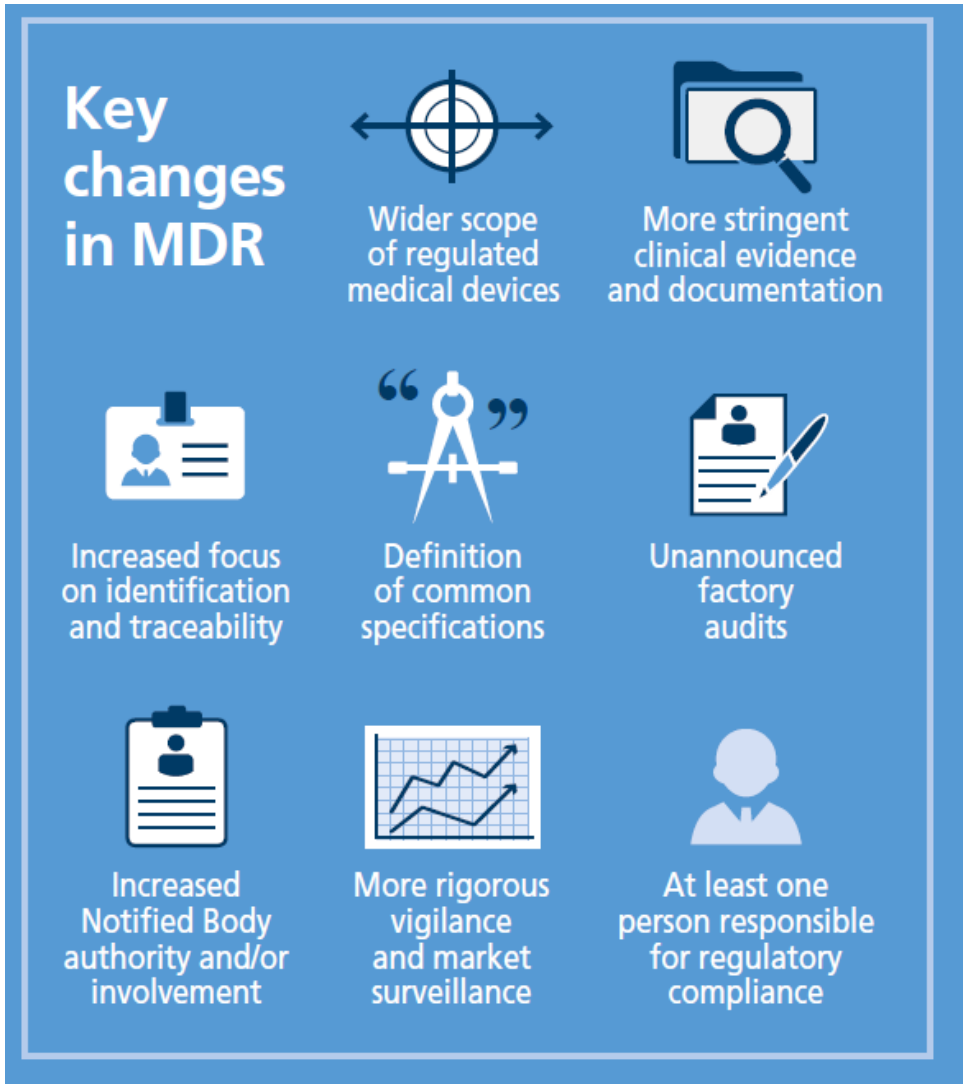
https://www.youtube.com/watch?v=fM1SYSFlIUE

Timelines



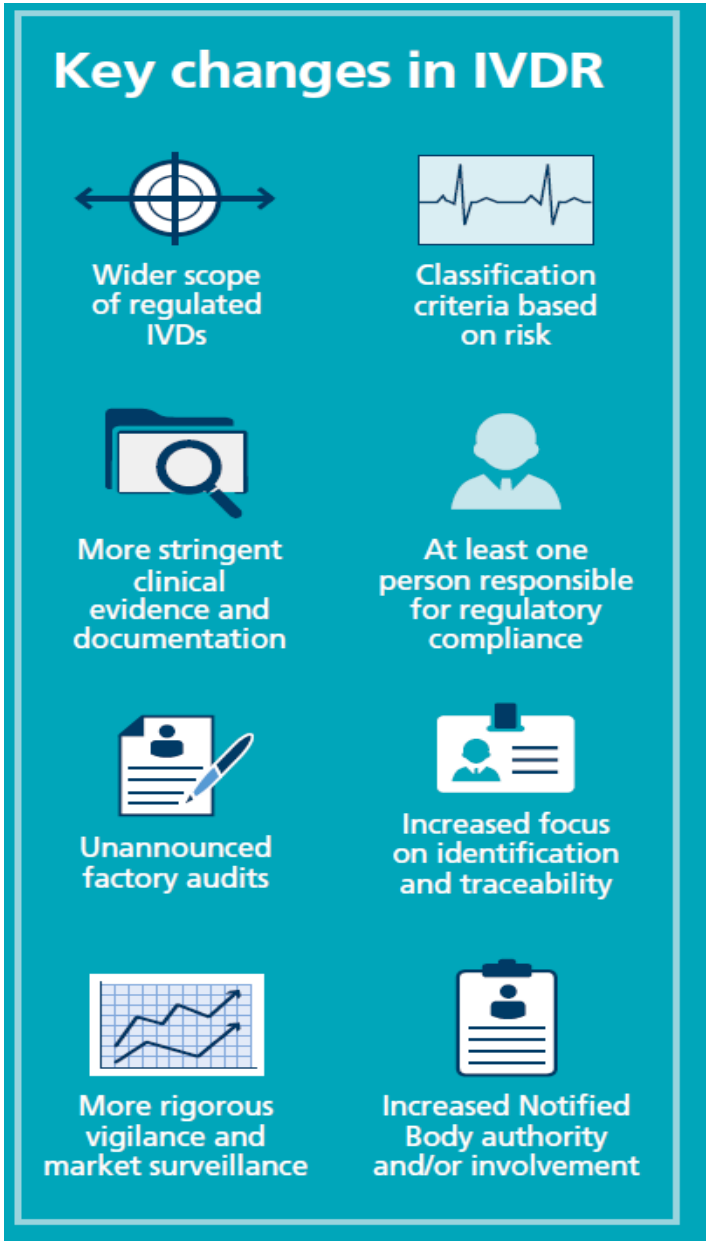
Source - MHRA

Key Changes



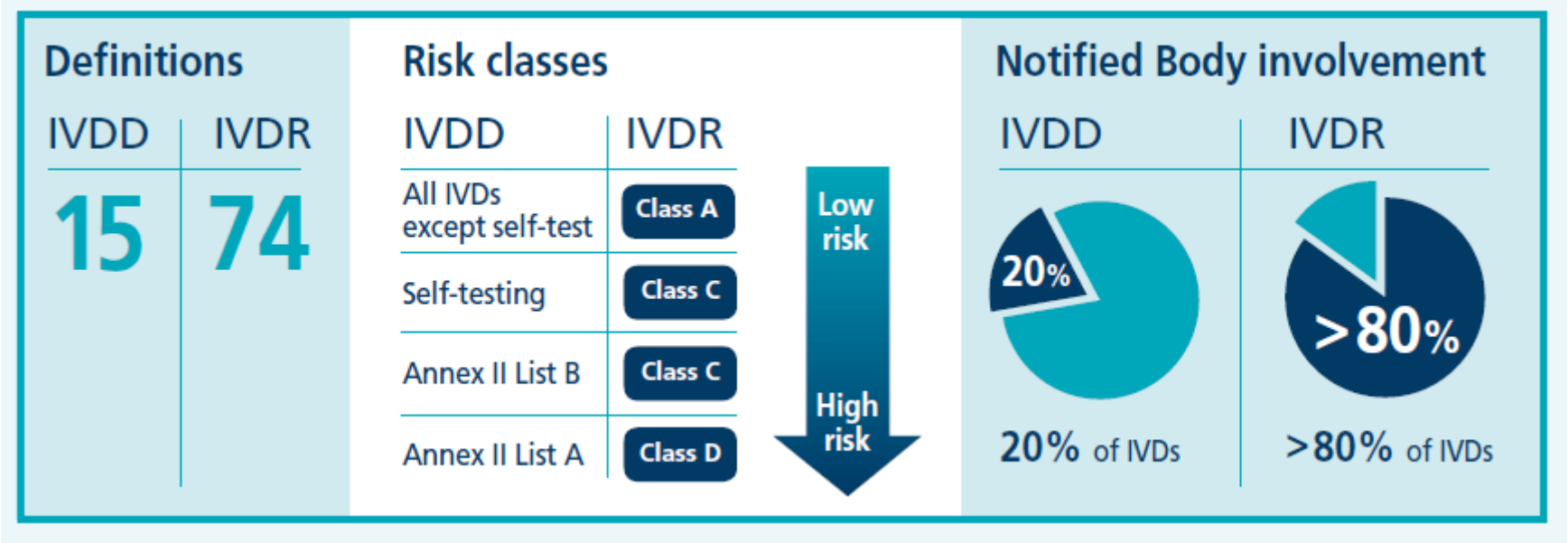
Source - LRQA

Key Changes



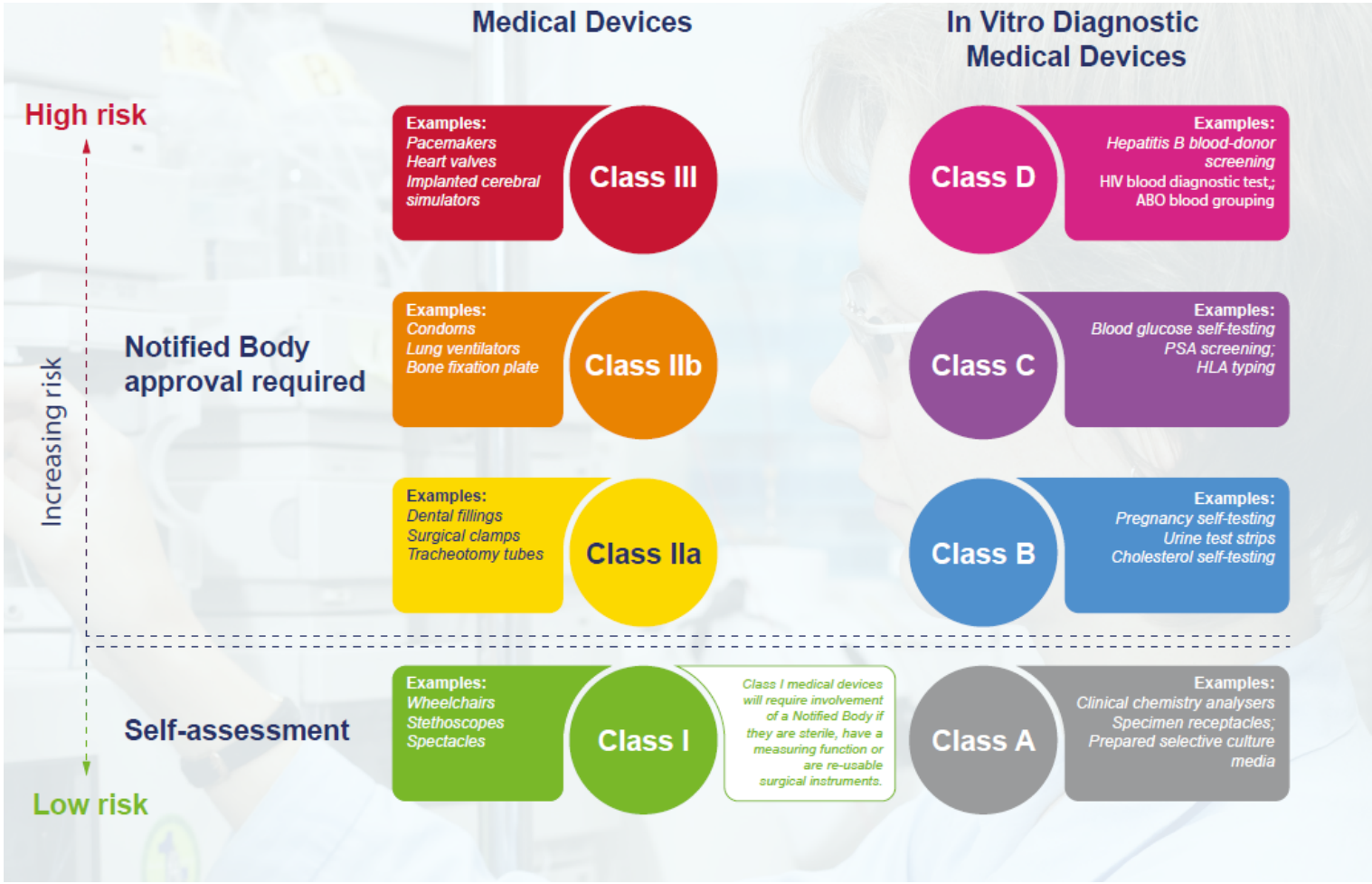
Source - LRQA

Other areas of Impact - IVDR



Source - LRQA

Risk and Classification



Source - MHRA

Notified Bodies – Impact – Articles 35 - 50

- 5 Notified Bodies in UK
- 29 in EU
- Rumours of NBs pulling out of Medical Device certification
- Increased workload on contracting resource will cause major pushback on manufacturers

Member list
On May, 1th 2013

Identification Number	Notified Body	Country
2138	ALBERK QA TECHNİC	TR
0473	AMTAC SYSTEM CERTIFICATIONS	UK
0535	BSI Germany	D
0086	BSI PRODUCT CERTIFICATION	UK
0124	DEKRA Certification GmbH	D
0344	DEKRA Certification B.V.	NL
0543	DGM Presafe	DK
0434	DNV Presafe AS	N
0297	DQS	D
1011	EMKI	HUN
1023	ITC Institute for Testing and Certification	CZ
0413	INTERTEK SEMKO	S
1984	Kiwa Meyer Certification Services	TR
0459	LNE - G-MED	F
1275	LGA InterCert GmbH	D
0088	LRQA	UK
0483	MDC	D
0482	MEDCERT	D
0470	NEMKO Presafe AS	NO
0050	NSAI	IRL
1868	OTDM CERTIFICARE	RO
0120	SGS	UK
1304	SIQ	SI
2195	SZUTEST	TR
0408	TÜV AUSTRIA	A
0044	TÜV NORD	D
0197	TÜV Rheinland LGA Products GmbH	D
0123	TÜV SÜD	D
2292	UDEM	TR

Source – Team NB

Additional Changes –

- Were 24 articles, now 123 articles
- Were 12 Annexes, now 17 Annexes
- More focus on novel technologies, combination, software etc.
- Changes in Classifications some Class IIa is IIb, some Class IIb to Class III
- Large changes to Economic operators – suppliers etc.
- PSUR
- Implementing and Delegating acts
- Common Specifications where no harmonised standards exist
- Autorised Rep – increased responsibilities
- NBs major changes

Widened Scope

The classification ruling of Medical Devices from the previous MDD And the IVDD is much broader now which classifies more products as Devices, such as cosmetic implants, contact lenses, wearable devices With a medical function, new rules for special cases.

Due to the ever changing technological landscape the regulation is Designed to capture all variables and allow for classification.

Heavy focus on Clinical Evidence –
Articles 61 – 82, Annex XIV, XV: MDR
Articles 56 – 77, Annex XIII, Annex XIV - IVDR

- Med Dev 2.7.1 Rev 4 Clinical Evaluation : A guide for manufacturers and Notified Bodies was revised in July 2016, a focus on more Clinical Evidence was already triggered.
- Definitions expanded
- Under new rules CER (Clinical Evaluation Report) is mandatory
- Equivalencies must be identical
- Clinical plans must be scientifically valid
- Sampling
- Relevant to technology

Identification and Traceability – UDI – Articles 25 -34, Annex VI

- Unique Device Identification, follows GUDID from FDA which was triggered in 2014

- Eudamed Database in progress to be available 2019 September
- Impacts all economic operators
- Resources needed – Labelling experts, validation engineers,
- vision inspection, barcode reader, printing technology, IT infrastructure- NOT JUST LABELS!

UDI must be placed on the Label and reported to EUDAMED within 1 to 5 years after the Date of Application according to the device class

Device Class	UDI On Label & Reported to EUDAMED*	UDI Direct Mark on Reusable
MD-Class III & Implantables	26 May 2021	26 May 2023
MD-Class IIa & IIb	26 May 2023	26 May 2025
MD-Class I	26 May 2025	26 May 2027
IVD-Class D	26 May 2023	26 May 2023
IVD-Class B & C	26 May 2025	26 May 2025
IVD-Class A	26 May 2027	26 May 2027

* Report to UDI System (EUDAMED) before placing on market

Unannounced Visits – Annex VII

- Minimum once every 3 years
- Following FDA trends
- Higher frequency based on risk, media reports etc.
- Will be reviewing that Quality system operates properly
- Gives Notified bodies more authority
- Designed to detect fraudulent activities
- Ensure your procedures allow for unannounced visits
- Communicate planned shutdowns with NBs

Regulatory Compliance person – Article 15

- Manufacturers & Authorised Reps should have at least one person responsible for Regulatory compliance
- With either a diploma or relevant qualification or
- 4 years of professional experience in reg affairs or in QMS relating to Medical devices

Increase focus on PMS Article 83, Annex III. XIV and Vigilance – Article 87-92

- One of the most important areas of the regulations to ensure Manufacturers stay in control of their QMS
- Conduct FSCA (Field Safety Corrective Actions)
- Data gathering to update – Risk Management, IFU & Labels, Clinical Evaluation, Safety and Performance (Essential Requirements), CAPA,
- Plan and Report
- PSUR (Periodic Safety Update Report) – Article 86 (Class IIa/b and III)
- Vigilance – reactive, - trend reporting, analysis of serious incidents and FSCA

Common Specifications, Implementing and Delegating Acts – Article 81, 91

Article 9 – Where no harmonised standard exist common specifications Will be used for general safety and performance requirements, Technical documentation and clinical evidence.

Implementing and Delegating Acts

Its not clear what the Implementing and Delegating acts will contain But will ensure proper application of the regulations

Essential Requirements now General Safety and Performance Requirements - Annex I

- Can use the IMDRF format or use your own

- More requirements and more detail requested – more than 100 items

- Chapter I – General Requirements
- Chapter II – Requirements regarding Design and Manufacture – most extensive!!!!
- Chapter III – Requirements regarding the Information supplied with the Device – Label/ IFU

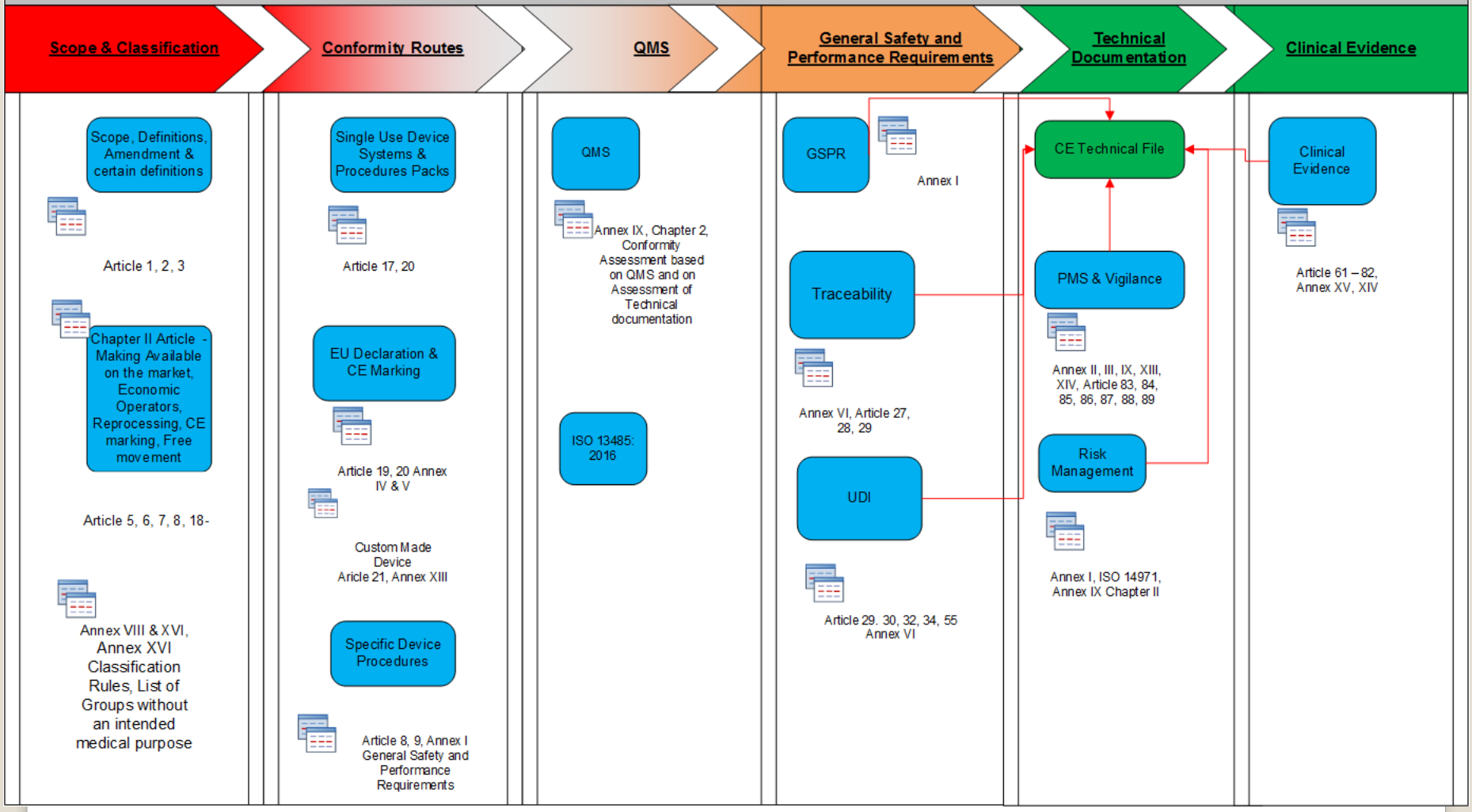
- Use harmonised standards or Common Specifications (when released)

Resources

Activity	Resources needed
Clinical Data	Clinical Specialists, CRO
Post Market Surveillance	Complaint Specialists
UDI	Packaging/UDI Engineers
Project Management	Project Manager
Ensure all levels of compliance	• Regulatory Affairs Specialists • Quality Engineers • Validation Experts • CAPA consultants • Subject Matter Experts
Audit	• Notified Body

Part Two – Guidelines in Product launch

Regulatory Path – with MDR references further detail



Regulatory Path – with IVDR references further detail