

Commercial readiness in light of IVDR



Meet our speakers



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Diagnostics & Principal
Consultant

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**Mehr Sicherheit.
Mehr Wert.**

**Choose certainty.
Add value.**

Impact of the new device classification under IVDR

Julien Senac, Ph.D.

In Vitro Diagnostic Device - Definition

'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether **used alone or in combination**, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally **for the purpose of providing information on one or more of the following**:

- a. concerning a physiological or pathological process or state;
- b. concerning congenital physical or mental impairments;
- c. concerning the predisposition to a medical condition or a disease;
- d. to determine the safety and compatibility with potential recipients;
- e. to predict treatment response or reactions;
- f. to define or monitoring therapeutic measures.

IVD classification

Directive 98/79/EC (IVDD)

Article 9: Conformity assessment

Products

Annex II List A

Annex II List B

Self-Testing devices

Other products

Regulation EU 2017/746 (IVDR)

Chapter V: Classification and conformity assessment

Article 47: Classification of products

Annex VIII – Classification rules

- Implementing rules
- Classification rules (Rules 1 – Rules 7)

Products – Risk-class

Class D

Class C

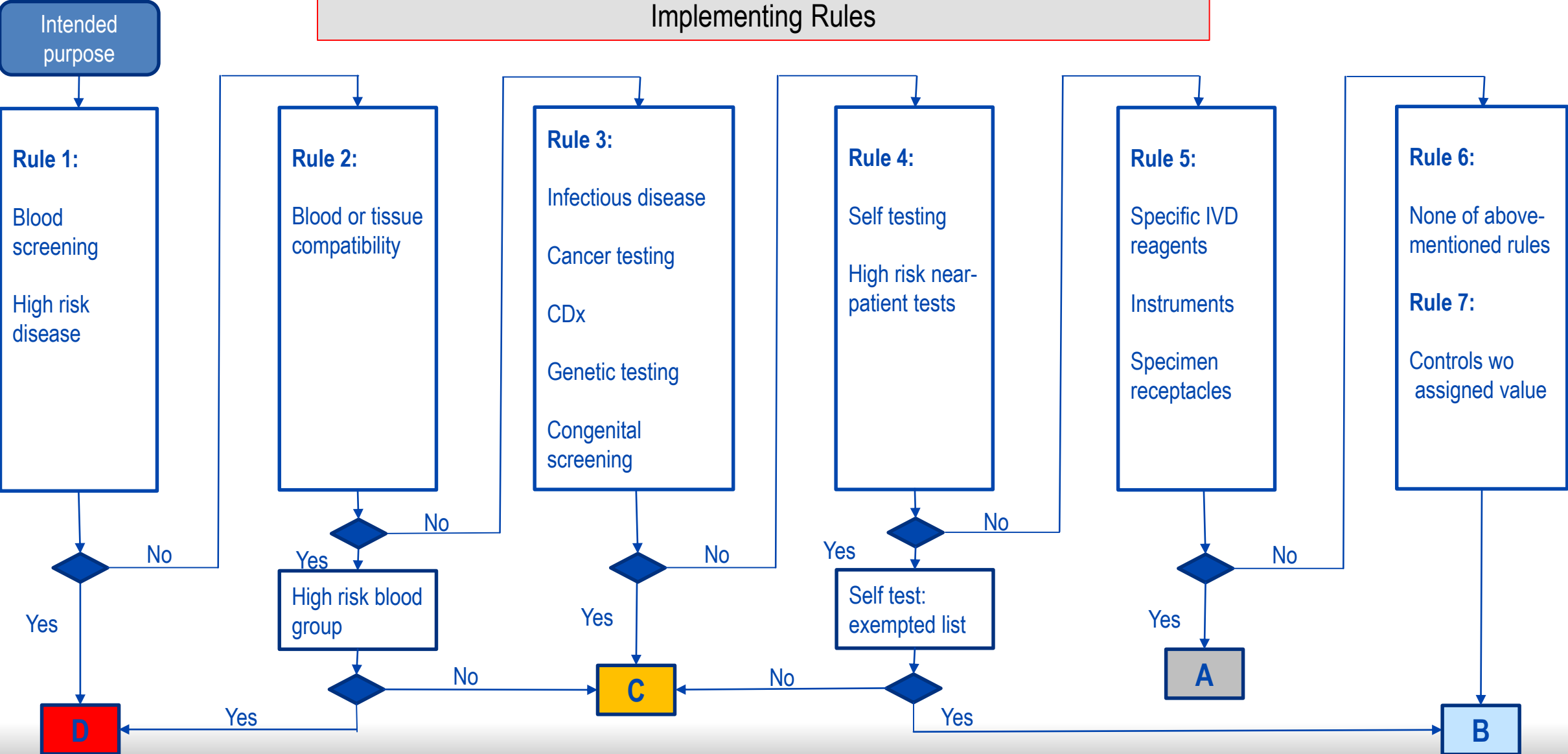
Class B

Class A

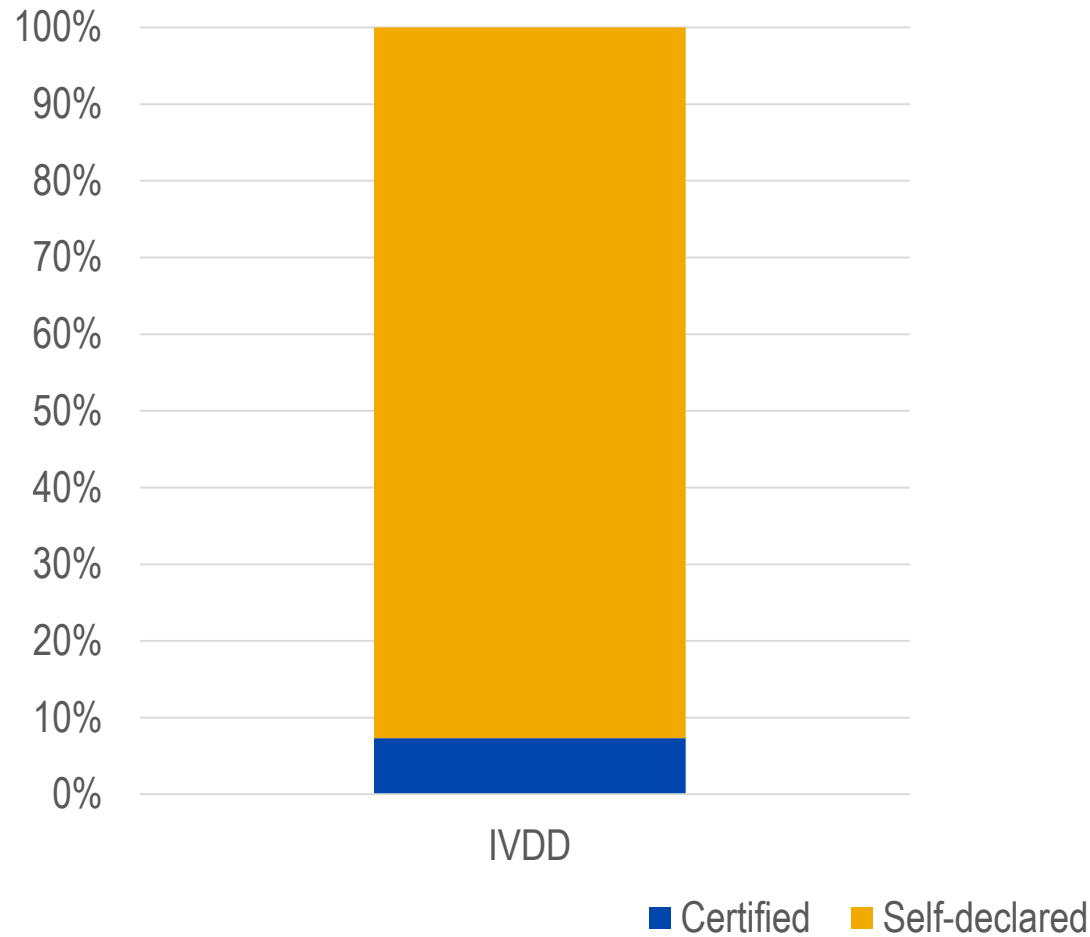
(Self-testing or near-patient devices, companion diagnostics)

IVD classification

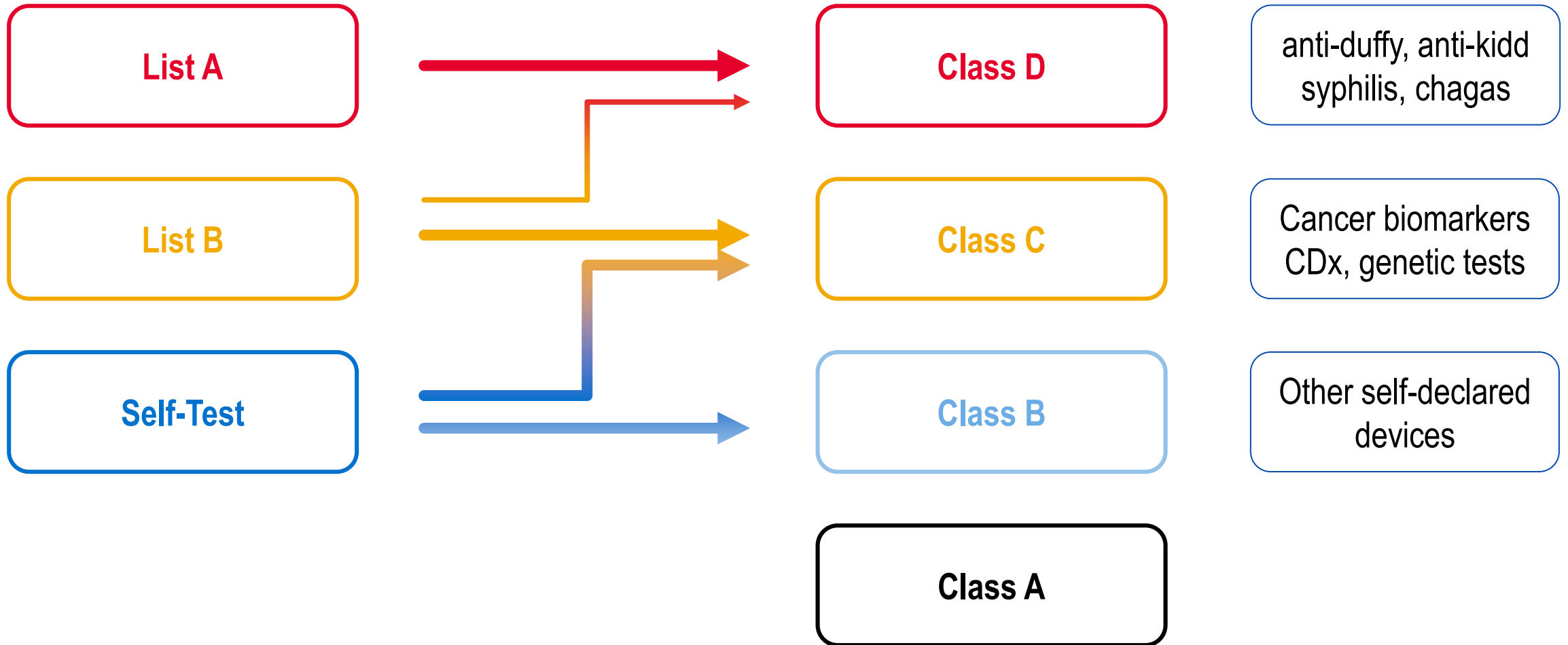
Implementing Rules



New classification impact



New classification impact



New classification impact – Interpretation

MDCG 2020-16

Guidance on Classification Rules for *in vitro* Diagnostic Medical Devices under Regulation (EU) 2017/746

November 2020

New classification impact – Don't forget software

MDCG 2019-11

**Guidance on Qualification and Classification
of Software in Regulation (EU) 2017/745 – MDR
and Regulation (EU) 2017/746 – IVDR**

October 2019

New classification (non) impact

Plans for all devices

- Strategy for Regulatory Compliance (Article 10 & Annex IX)
- Risk Management Plan (Annex I)
- Performance Evaluation Plan (Article 56 & Annex XIII)
- Performance Study Plan (Annex XIII)
- Post-Market Surveillance Plan (article 79 & Annex III)
- Post-Market Performance Follow-up Plan (Annex XIII)

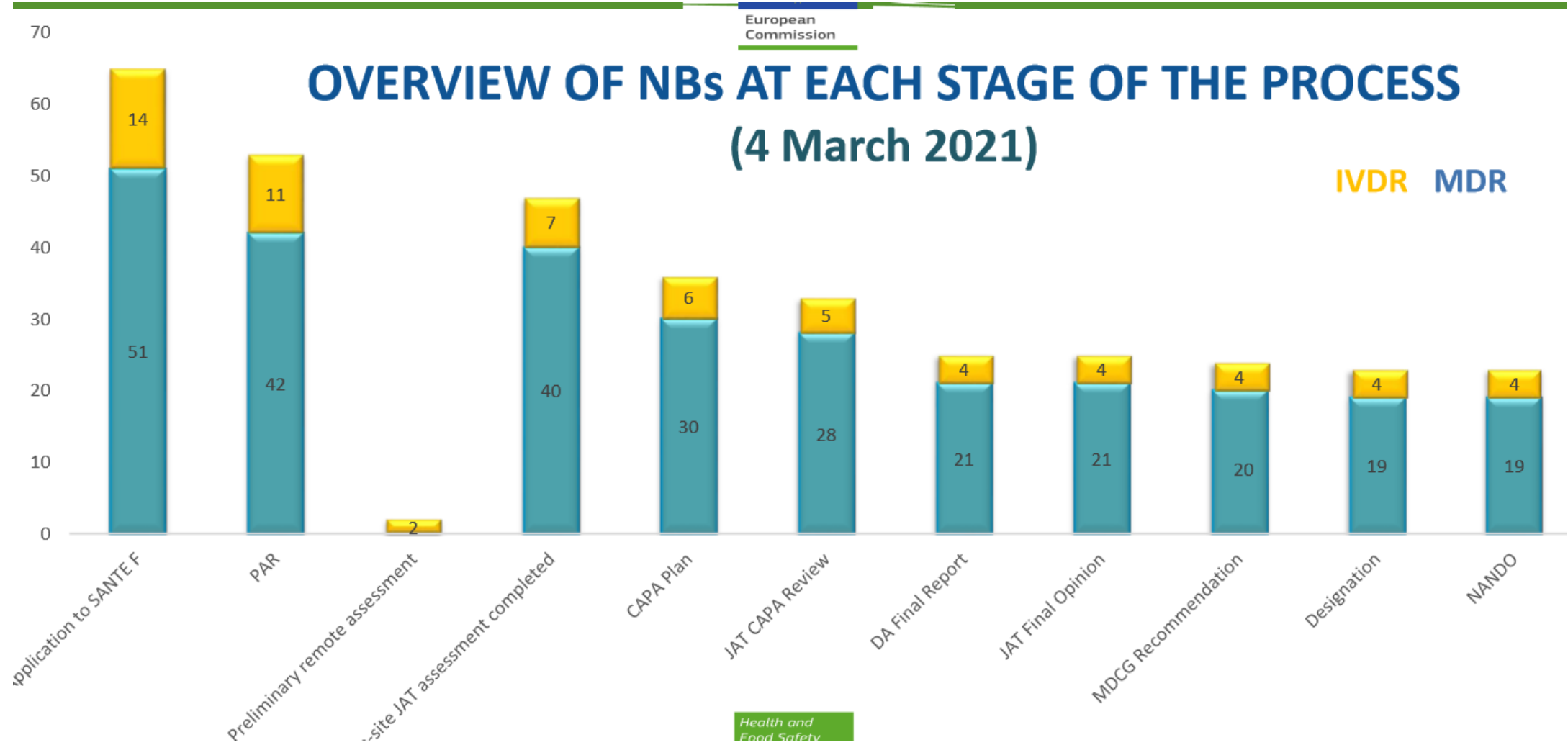
Reports for all devices

- Risk Management Report (Article 10 & Annex I)
- Scientific Validity Report (Annex XIII)
- Analytical Performance Report (Annex XIII)
- Clinical Performance Report (Annex XIII)
- Performance Evidence Report (Annex XIII)
- Clinical Performance Study report (Annex XIII)
- Post-Market Surveillance Report (Article 80)
- Periodic Safety Update Report or PSUR (Article 81) (C and D)
- Periodic Summary report (Article 82) (A and B)
- Trending report (Article 83)
- Post-Market Performance Follow-up Report (Annex XIII)
- Summary of Safety and Performance or SSP (Article 29)
- IFU/Labeling (Document) (Chapter III, Annex I)
- Claims (Document) (Article 7)
- Declaration of Conformity (Annex IV)

What should I do with my portfolio?

- Determine which products will be maintain on the market
- Clearly define the intended purpose according to Annex II, exclude claims to avoid ambiguity
- Determine the class of the product and discuss it with NB
- Renew certificates for List A, List B, and self-tests
- Prioritize my entire portfolio
- Anticipate the bottleneck

New classification impact



? QUESTIONS ?

спасибо 谢谢
GRACIAS

THANK YOU

ありがとうございました MERCI

DANKE धन्यवाद

شُكراً **OBRIGADO**

Gracie

감사합니다



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ECONOMIC OPERATORS AND THE EXITS

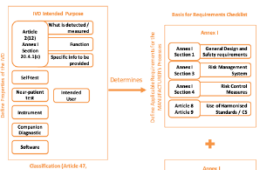
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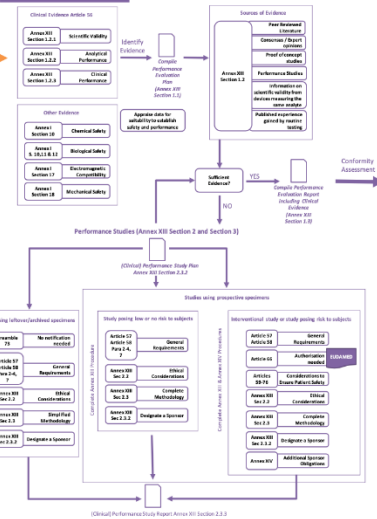
For more information please contact the regulatory & medical policy department: regulatory@medtech.europa.org



Design



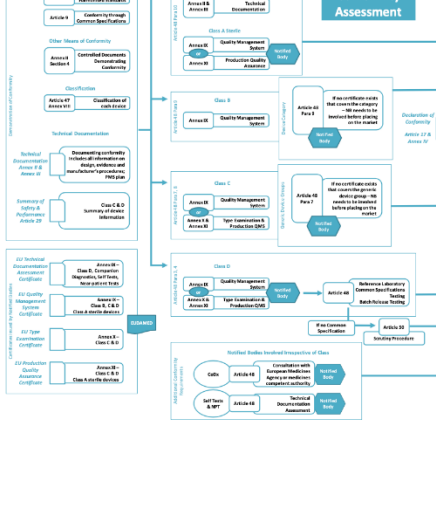
Evidence Collection



Obligations of Manufacturers

Article	Paragraph	Requirement	Category
Article 10	Paragraph 1	Risk Management System	General
Article 10	Paragraph 2	Performance evaluation	General
Article 10	Paragraph 3	Technical documentation	General
Article 10	Paragraph 4	Conformity assessment	General
Article 10	Paragraph 5	EU registration	General
Article 10	Paragraph 6	Availability of technical file	General
Article 10	Paragraph 7	Quality Management System	General
Article 10	Paragraph 8	EMR, vigilance	General
Article 10	Paragraph 9	Essential requirements	General
Article 11	Paragraph 1	Essential requirements	General
Article 11	Paragraph 2	Essential requirements	General
Article 11	Paragraph 3	Essential requirements	General
Article 11	Paragraph 4	Essential requirements	General
Article 11	Paragraph 5	Essential requirements	General
Article 11	Paragraph 6	Essential requirements	General
Article 11	Paragraph 7	Essential requirements	General
Article 11	Paragraph 8	Essential requirements	General
Article 11	Paragraph 9	Essential requirements	General
Article 11	Paragraph 10	Essential requirements	General
Article 11	Paragraph 11	Essential requirements	General
Article 11	Paragraph 12	Essential requirements	General
Article 11	Paragraph 13	Essential requirements	General
Article 11	Paragraph 14	Essential requirements	General
Article 11	Paragraph 15	Essential requirements	General
Article 11	Paragraph 16	Essential requirements	General
Article 11	Paragraph 17	Essential requirements	General
Article 11	Paragraph 18	Essential requirements	General
Article 11	Paragraph 19	Essential requirements	General
Article 11	Paragraph 20	Essential requirements	General
Article 11	Paragraph 21	Essential requirements	General
Article 11	Paragraph 22	Essential requirements	General
Article 11	Paragraph 23	Essential requirements	General
Article 11	Paragraph 24	Essential requirements	General
Article 11	Paragraph 25	Essential requirements	General
Article 11	Paragraph 26	Essential requirements	General
Article 11	Paragraph 27	Essential requirements	General
Article 11	Paragraph 28	Essential requirements	General
Article 11	Paragraph 29	Essential requirements	General
Article 11	Paragraph 30	Essential requirements	General
Article 11	Paragraph 31	Essential requirements	General
Article 11	Paragraph 32	Essential requirements	General
Article 11	Paragraph 33	Essential requirements	General
Article 11	Paragraph 34	Essential requirements	General
Article 11	Paragraph 35	Essential requirements	General
Article 11	Paragraph 36	Essential requirements	General
Article 11	Paragraph 37	Essential requirements	General
Article 11	Paragraph 38	Essential requirements	General
Article 11	Paragraph 39	Essential requirements	General
Article 11	Paragraph 40	Essential requirements	General
Article 11	Paragraph 41	Essential requirements	General
Article 11	Paragraph 42	Essential requirements	General
Article 11	Paragraph 43	Essential requirements	General
Article 11	Paragraph 44	Essential requirements	General
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Article 11	Paragraph 46	Essential requirements	General
Article 11	Paragraph 47	Essential requirements	General
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Article 11	Paragraph 50	Essential requirements	General
Article 11	Paragraph 51	Essential requirements	General
Article 11	Paragraph 52	Essential requirements	General
Article 11	Paragraph 53	Essential requirements	General
Article 11	Paragraph 54	Essential requirements	General
Article 11	Paragraph 55	Essential requirements	General
Article 11	Paragraph 56	Essential requirements	General
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Article 11	Paragraph 99	Essential requirements	General
Article 11	Paragraph 100	Essential requirements	General

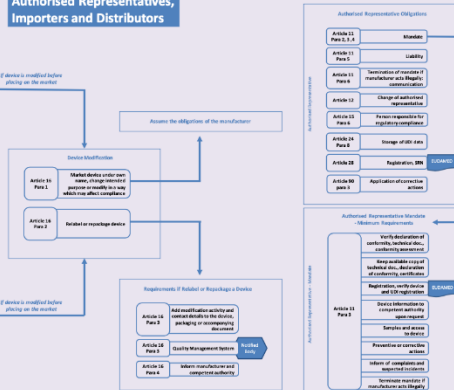
Conformity Assessment



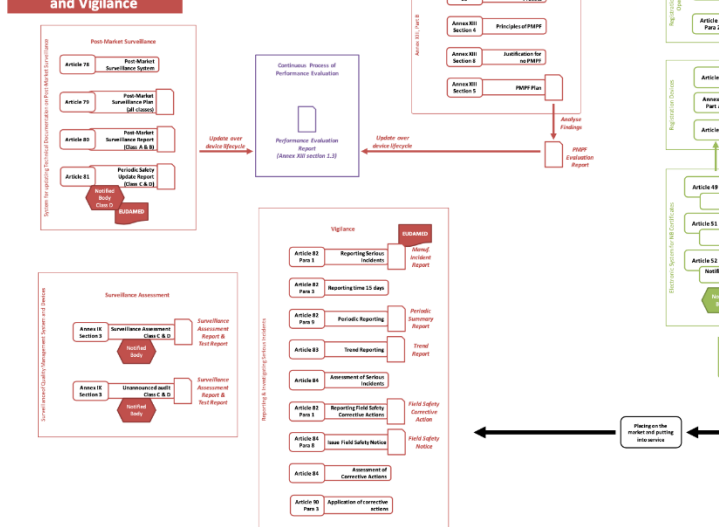
Registration



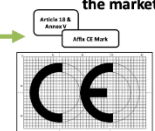
Obligations of Authorised Representatives, Importers and Distributors



Post-Market Surveillance and Vigilance



Placing on the market



Articles 10 & Annexes
Annex CE Mark

Obligations of Authorised Representatives, Importers and Distributors

Importer Obligations

Requirements for Importers

Article 13 Para 1,2	Verify device compliance	
Article 13 Para 3	Add contact details to device or packaging or accompanying document	
Article 13 Para 4	Verify device registration, add own details	EUDAMED
Article 13 Para 5	Safeguard storage and transport conditions	
Article 13 Para 6	Keep register of complaints, non-conforming devices, etc.	
Article 13 Para 7	Inform of non-conformities and serious risk	
Article 13 Para 7	Ensure implementation of corrective actions	
Article 13 Para 8	Inform of complaints & suspected incidents	
Article 13 Para 9	Keep Declaration of Conformity and certificate(s)	
Article 13 Para 10	Cooperation with Competent Authorities	
Article 22	Identification within the supply chain	
Article 24 Para 8	Storage of UDI data	
Article 27 Para 3	Verify registration of manufacturer or authorised representative; add own details	EUDAMED
Article 28	Registration of the importer	EUDAMED
Article 90 Para 3	Application of corrective actions	

Within 2 weeks of placing on market

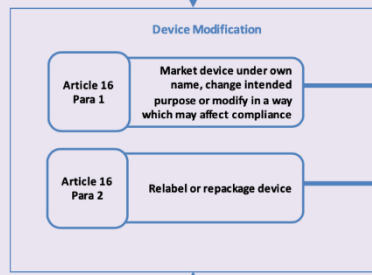
Distributor Obligations

Requirements for Distributors

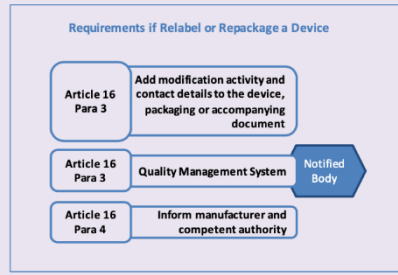
Article 14 Para 2	Verify device compliance	Sampling method
Article 14 Para 3	Safeguard storage and transport conditions	
Article 14 Para 4	Inform of non-conformities and serious risk	
Article 14 Para 4	Ensure implementation of corrective actions	
Article 14 Para 5	Inform of complaints & suspected incidents	
Article 14 Para 5	Keep register of complaints, non-conforming devices, etc.	
Article 14 Para 6	Cooperation with Competent Authorities	
Article 22	Identification within the supply chain	
Article 24 Para 8	Storage of UDI data	
Article 27 Para 2	Distributor Registration	National Database
Article 90 para 3	Application of corrective actions	

If device is modified before placing on the market

If device is modified before placing on the market



Assume the obligations of the manufacturer



Authorised Representative Obligations

Authorised Representative

Article 11 Para 2, 3, 4	Mandate
Article 11 Para 5	Liability
Article 11 Para 6	Termination of mandate if manufacturer acts illegally: communication
Article 12	Change of authorised representative
Article 15 Para 6	Person responsible for regulatory compliance
Article 24 Para 8	Storage of UDI data
Article 28	Registration, SRN
Article 90 para 3	Application of corrective actions

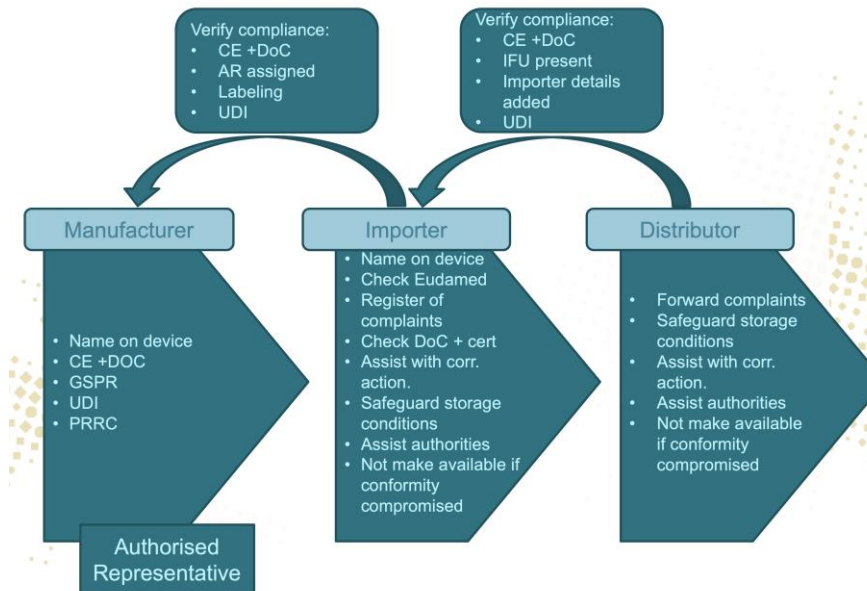
Authorised Representative Mandate - Minimum Requirements

Authorised Representative - Mandate

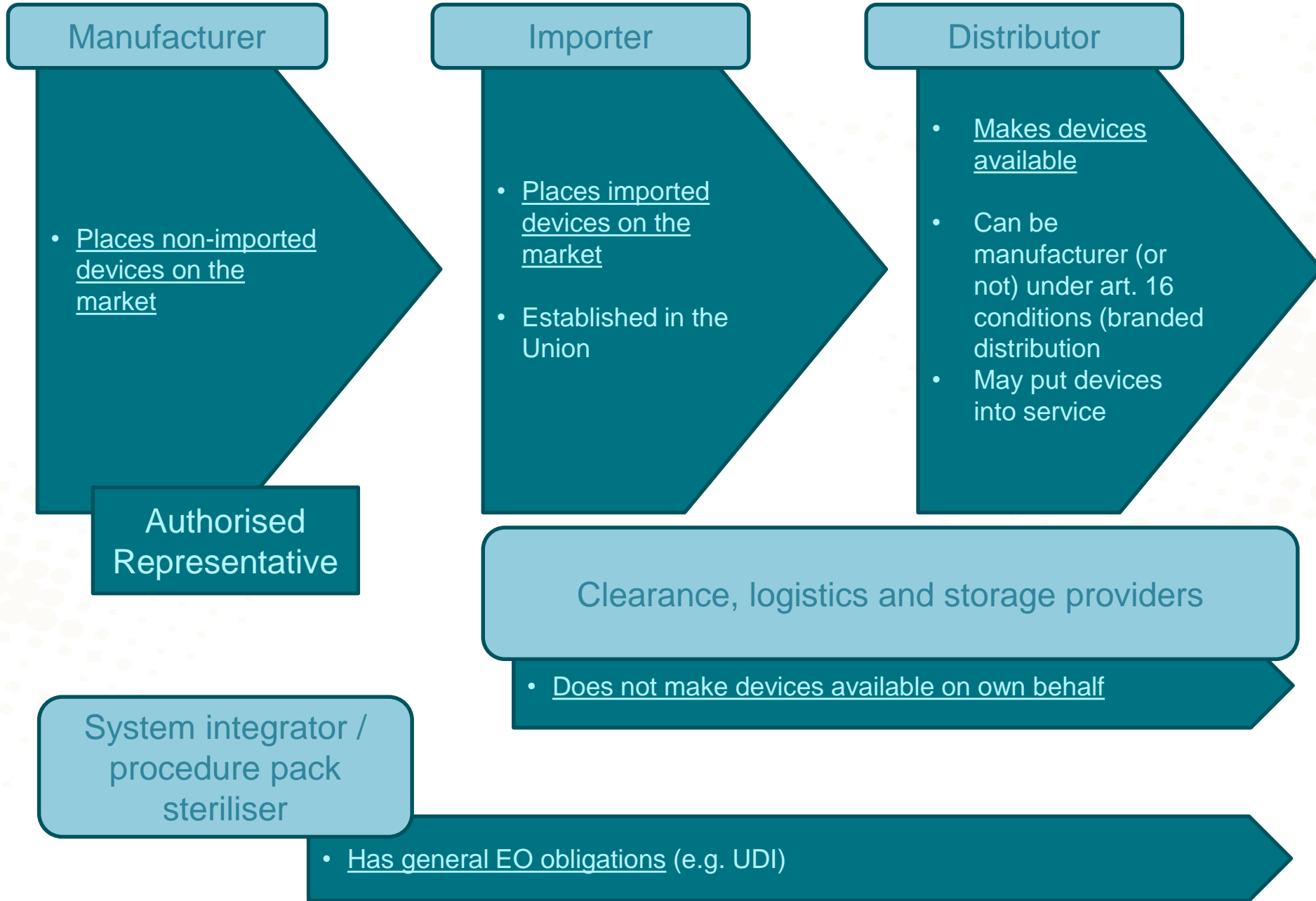
Article 11 Para 3	Verify declaration of conformity, technical doc., conformity assessment
	Keep available copy of technical doc., declaration of conformity, certificates
	Registration, verify device and UDI registration
	Device information to competent authority upon request
	Samples and access to device
	Preventive or corrective actions
	Inform of complaints and suspected incidents
	Terminate mandate if manufacturer acts illegally

Economic operators

- Understand new supply chain rules and what they mean for
 - contracts with third parties in the supply chain
 - the company's own supply chain
- Update / renegotiate agreements where necessary or opportune
- Use MDR as opportunity for more cooperative supply chain model to achieve your PMCF data goals
 - Or be prepared for questions and NCs during NB audits



How to qualify economic operator?



How to qualify economic operator?

Understanding of concepts of “placing on the market” and “making available” crucial for EO characterisation

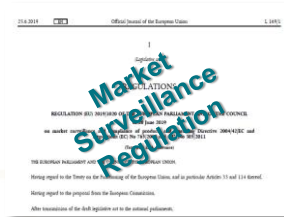
Placing on the market

- first transfer of a device from the manufacturing stage into the Union distribution chain after final quality control release as finished goods (includes packaging or labelling); and
- the device must be freely available for supply or final use within the Union supply chain (customs cleared and intent to distribute in Union)

Making available

- device must be supplied for distribution, consumption or use in the Union in the course of a commercial activity, either for payment or free of charge
- Implies offer or agreement, physical handover not required

Toolbox EOs: understand these to understand EO



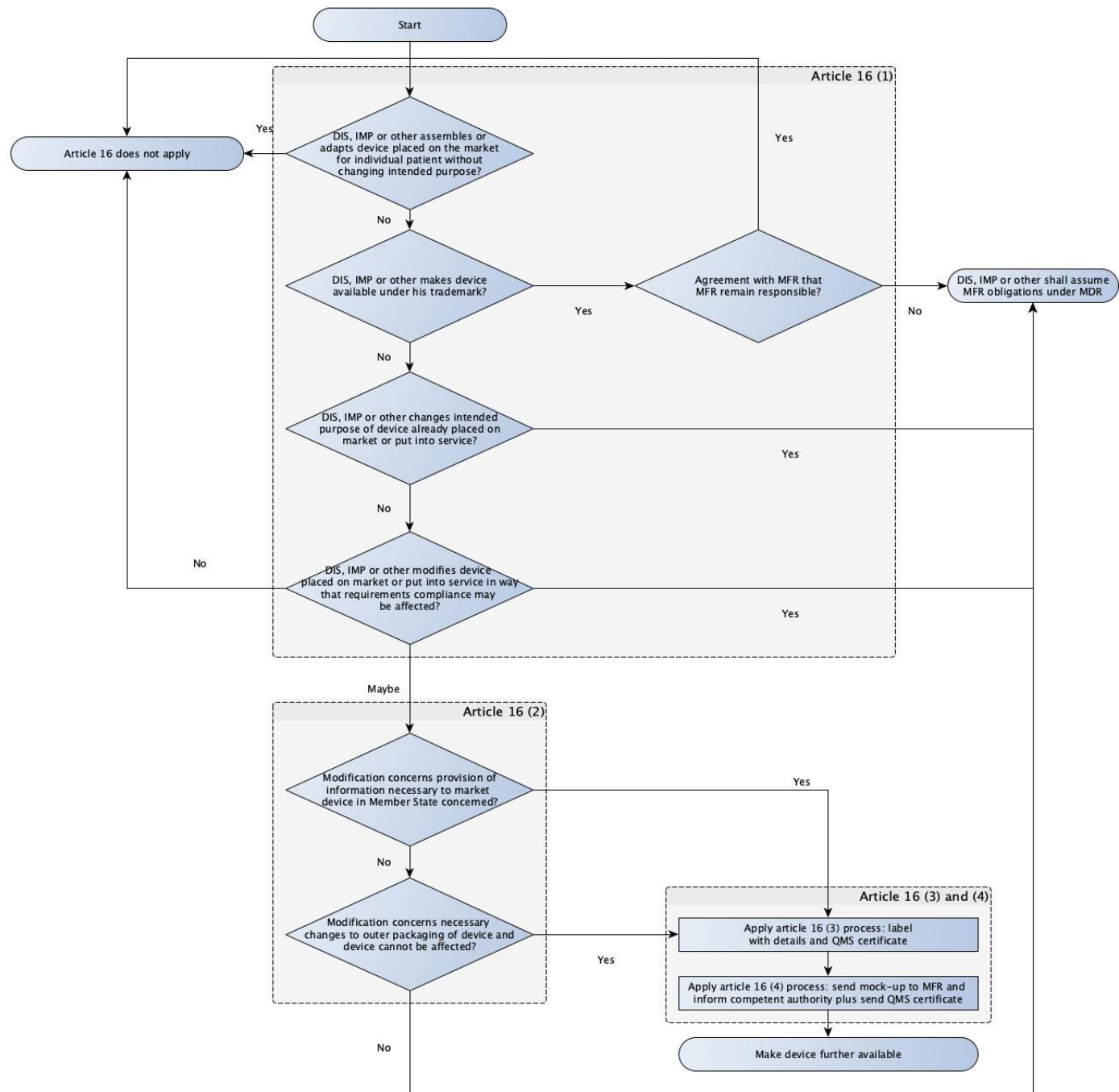
Be prepared to educate your company's legal department to avoid costly mistakes

Supply and distribution agreements

- Wholesalers – also qualify as importers or distributors even if they don't want to
- How to work together for
 - autonomous obligations of importers and distributors
 - overlapping responsibilities in supply chain
 - Article 25 MDR obligation of traceability
- Manufacturer must be able to demonstrate for PMS plan purposes that he leverages PMS information in supply chain (Annex III, 1.1 and 1.2)
 - Goes beyond mere complaints logging and vigilance
 - E.g. ensure access to article 13 (5) MDR/IVDR distributor registers of user/patient complaints, non-conforming devices, recalls and withdrawals
- Requires careful and precise revisions of agreements


Third parties: repacking & relabelling

- Basically pharma repacking case law written down for devices
- Strangely enough stricter regime than outcome of the EU Court Servoprax case (C-277/15) and Lohman & Rauscher Case (C-662/15)
- Article 16 (2) – (4) MDR/IVDR:
 - Translation of IFU and other information and repacking do not make someone a manufacturer
 - “necessary”
 - Indicated person responsible for activity on the pack or accompanying document
 - Have notified body blessed QMS for activity and have access to manufacturer vigilance action
 - Reporting and mock-up to manufacturer and NCA for each time repacked / relabelled device is made available



Exits

- Brexit – happened
31/12/20
- Swixit – likely
26/05/21
- Turkxit – maybe
26/05/21

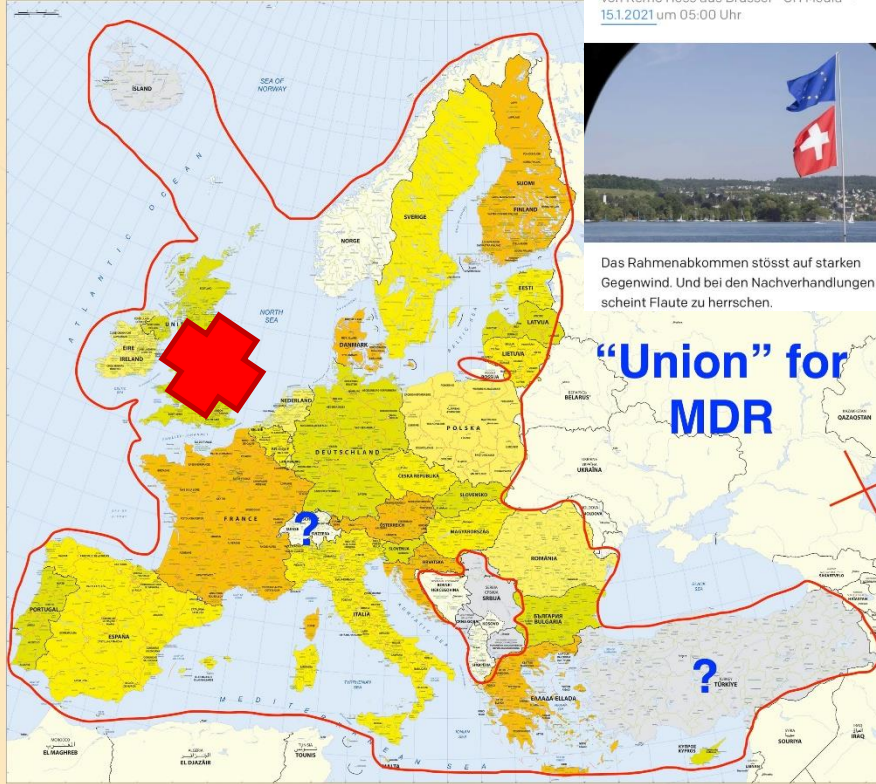


ALLE NEWS


RAHMENABKOMMEN

Corona, keine Zeit und keine Lust: Warum die Schweiz und die EU nicht ins Gespräch kommen

von Remo Hess aus Brüssel - CH Media · 15.1.2021 um 05:00 Uhr



"Union" for MDR



Das Rahmenabkommen stößt auf starken Gegenwind. Und bei den Nachverhandlungen scheint Flaute zu herrschen.

European Union Member States	Population	GDP	Area
Austria	8.9M	45.5B	83.9k
Belgium	11.5M	45.5B	30.5k
Bulgaria	7.5M	45.5B	110.9k
Croatia	4.4M	45.5B	56.5k
Cyprus	0.8M	45.5B	9.2k
Denmark	5.6M	45.5B	43.1k
Estonia	1.3M	45.5B	45.2k
Finland	5.5M	45.5B	143.9k
France	67.1M	45.5B	643.8k
Germany	82.7M	45.5B	357.4k
Greece	11.5M	45.5B	131.9k
Hungary	10.1M	45.5B	93.0k
Ireland	4.6M	45.5B	70.3k
Italy	60.3M	45.5B	301.3k
Lithuania	3.0M	45.5B	65.3k
Luxembourg	5.8M	45.5B	1.6k
Malta	0.4M	45.5B	316.0k
Netherlands	17.1M	45.5B	41.5k
Poland	38.1M	45.5B	312.7k
Portugal	10.9M	45.5B	69.3k
Romania	21.3M	45.5B	238.4k
Slovakia	5.4M	45.5B	49.0k
Slovenia	2.1M	45.5B	20.2k
Spain	45.9M	45.5B	505.0k
Sweden	10.1M	45.5B	45.2k
Turkey	74.7M	45.5B	783.5k
Average	12.5M	45.5B	130.0k

Country	Population	GDP	Area
UK	67.1M	245.5B	243.6k
Switzerland	8.5M	45.5B	41.3k
Norway	5.4M	45.5B	385.2k
Denmark	5.6M	45.5B	43.1k
Finland	5.5M	45.5B	143.9k
Sweden	10.1M	45.5B	45.2k
Poland	38.1M	45.5B	312.7k
Czechia	10.7M	45.5B	78.9k
Slovakia	5.4M	45.5B	49.0k
Hungary	10.1M	45.5B	93.0k
Romania	21.3M	45.5B	238.4k
Bulgaria	7.5M	45.5B	110.9k
Greece	11.5M	45.5B	131.9k
Turkey	74.7M	45.5B	783.5k
Ukraine	45.7M	45.5B	603.7k
Belarus	9.4M	45.5B	203.6k
Armenia	2.9M	45.5B	29.7k
Georgia	7.9M	45.5B	69.7k
Azerbaijan	10.1M	45.5B	86.6k
Iran	82.7M	45.5B	1.6M
China	1.4B	14.5B	9.6M
USA	331.0M	21.5B	9.8M
India	1.3B	2.5B	3.3M
Japan	125.8M	5.0B	377.9k
South Korea	51.7M	1.7B	100.0k
Australia	25.4M	1.3B	7.7M
Canada	38.1M	1.7B	9.9M
Brazil	213.1M	1.8B	8.5M
Mexico	128.1M	1.3B	1.9M
Argentina	45.7M	0.5B	2.8M
Colombia	51.7M	0.4B	1.1M
Vietnam	95.9M	0.3B	331.3k
Philippines	109.0M	0.3B	340.0k
Indonesia	270.6M	0.3B	1.9M
Thailand	65.4M	0.3B	513.1k
Singapore	5.7M	0.3B	719.0k
Malaysia	32.0M	0.3B	329.0k
South Africa	59.7M	0.3B	1.2M
Nigeria	206.1M	0.2B	923.0k
Egypt	101.3M	0.2B	1.0M
India	1.3B	0.2B	3.3M
China	1.4B	0.2B	9.6M
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Malaysia	32.0M	0.2B	329.0k
South Africa	59.7M	0.2B	1.2M
Nigeria	206.1M	0.2B	923.0k
Egypt	101.3M	0.2B	1.0M

MDR, IVDR and the Union

Official Journal of the European Union



English edition

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Contents

II *Information*

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

European Commission

2016/C 272/01


Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016 (*) 1

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Brexit



- Brexit agreement of Christmas 2020
 - Still not ratified by European Parliament
 - UK is now 'third' country for Union
 - No special rules for medical devices
 - UK notified bodies no longer Union NBs
 - UK allows CE marked devices on its market for fixed period; EU does not allow UK approved devices on EU market
 - UK starts with roll-out of UKCA system
 - UKCA devices
- 'Breaking Europe up from the inside didn't work, now back to breaking it up from the outside - it's called diplomacy'



INFORMATION FOR THE INDUSTRY

On 26 May 2021 the European Medical Device Regulation (MDR) will come into force, the same day that the corresponding Swiss Medical Device Ordinance (MedDO) enters into effect. All stakeholders must be aware that the Mutual Recognition Agreement (MRA) between Switzerland and the European Union (EU) will probably not be updated by 26 May 2021. It is also legally uncertain how the currently valid MRA of December 2017 will be interpreted by the EU Commission as of 26 May 2021. Regardless of all our efforts, Switzerland will probably become a third country in the area of medical devices on 26 May 2021. We offer practical assistance for the third country scenario:

Swiss manufacturers

- ↓ [Guidance for Swiss Manufactures \(in German\)](#)
- [Order Contract Template for EU Authorised Representative \(free for members, CHF 100.00 for non-members\)](#)

Swiss Distributors and Importers

- ↓ [Guidance for Swiss Distributors and Importers](#)
- ↓ [Information on importing medical devices into Switzerland](#)
- [Order Contract Template for Swiss Authorised Representative \(free for members, CHF 100.00 for non-members\)](#)

- MRA with Switzerland only covers medical devices and IVD directives and the transitional regime
- There is a negotiated Institutional Framework Agreement with the EU but this has not yet been approved at political level
 - So the EU pushes Switzerland out of the Union, one MRA at a time – end of May 2021 medical devices, end of May 2022 IVDs
 - Switzerland has synched its own Medizinprodukteverordnung (MepV) with the MDR and IVDR but misses mutual recognition without the IFA

Turkxit

- Turkey is linked to EU by Association Agreement that contains a customs union based on Decision 1/95, removal of technical barriers (Decision 1/97) and notification of Turkish notified bodies plus equivalence of CE and Turkish legislation for a number of EU directives, including those for medical devices and IVDs (Decision 1/2006)
- Same situation as Switzerland: legislation is aligned but are the MDR and IVDR on the list in time?
- Complex political situation between EU and Turkey
- European Commission: ‘all will be well, just one small personal data thing to take care of’
 - Yet: no Turkish MDR / IVDR NB so far, no EUDAMED for Turkey

▸ NB 1783	TURKISH STANDARDS INSTITUTION (TSE)	Turkey
▸ NB 1984	Kiwa Belgelendirme Hizmetleri A.Ş.	Turkey
▸ NB 2195	Szutest Uygunluk Değerlendirme A.Ş.	Turkey
▸ NB 2292	UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.	Turkey
▸ NB 2764	Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim Şirketi	Turkey

How to work with the exits?

- Blue Guide (new version underway)
 - Economic operators regime
 - Placing on the market
 - Importer
 - Authorised representative
- Brexit guidance industrial products version 13 March 2020
 - Economic operators
 - Notified bodies and certificates
 - Transitional regime and placing on the market around the transitional regime
 - Explain the complex NI situation (including UK(NI) marking by Irish notified bodies – which have their own NANDO page now:
<https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=ireland.main>)



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND
SMEs
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
DIRECTORATE-GENERAL FOR MOBILITY AND TRANSPORT
DIRECTORATE-GENERAL FOR JUSTICE AND CONSUMERS
DIRECTORATE-GENERAL FOR ENVIRONMENT
DIRECTORATE-GENERAL FOR ENERGY

Brussels, 13 March 2020
REV2 – replaces the notice (REV1)
dated 22 January 2018 and the
Q&A document dated 1 February
2019

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF INDUSTRIAL
PRODUCTS¹

Scenario anyone?



- Does your company have the possible scenarios managed?
 - I have an MDD certificate of a Turkish notified body for a device in a kit – they say it will all be fine after 26 May.
 - I'm a US multinational and my European supply chain runs via my importer in Switzerland for tax reasons, with the stock in a 3PL in the Netherlands.
 - I'm a manufacturer that sells a lot of IVDs into the UK. When do I need a UKCA mark for the devices?

Finally: the MSR, MDR and IVDR

- The Union becomes stronger and more tightly knit in terms of market surveillance
 - MDR market surveillance regime enters into force on 26 May 2021 (Chapter VII, section 3 MDR)
 - Market Surveillance Regulation (Regulation (EU) 1020/2019) by 16 July 2021 – applies to MDR en IVDD/IVDR and insofar as things are not regulated in MDR/IVDR
 - Especially relevant for devices in the fields of
 - Online sales (FSP responsibilities if you dropship via FSP)
 - Following first enforcement action by other competent authorities
 - Costs of enforcement may be charged to infringer

Thanks for your attention!



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The IVD, RUO or General Lab use?

Sue Spencer

IVD Lead Principal Consultant

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Scope of the IVDR

- Do I have an IVD, medical devices, general laboratory or research use only product?
- The IVDR does not apply to:
 - (a) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;
 - (b) invasive sampling products or products which are directly applied to the human body for the purpose of obtaining a specimen;
 - (c) internationally certified reference materials;
 - (d) materials used for external quality assessment schemes.

IVDR does not apply to medical devices, general lab or RUO!

General Laboratory Use

- No IVDR guidance
- IVDD Guidance
MEDDEV 2.14/1
Contains examples of product of general laboratory use and IVD
- However

	Laboratory use product	Covered by IVD Directive
Centrifuges	General centrifuges, cytopsin	Hematocrite centrifuge
Pipettes	General purpose pipettes (e.g. single or multiple pipettes, plastic pipettes, Pasteur pipettes)	Blood coagulation pipettes with automatic timing (Accessory of coagulometer)
Tubes and flasks	Erlenmeyers, plastic tubes	Blood collection tubes, urine sample containers
Plates	Empty ELISA plates, empty Petri dishes,	Coated microtiter plates for the diagnosis of Lyme's disease
Nucleic Acid extraction products	DNA and RNA extraction kits that only provide a specimen without an intended IVD detection combination	DNA and RNA extraction kits intended to provide a specimen to be used with an IVD device (validation for at least one combination is to be provided)
General equipment	Scales, balances, microtomes, incubators, sterilizers for laboratory equipment, paraffin embedding machine,	
HPLC products	size-exclusion HPLC columns	HPLC columns for IVD purposes: e.g. HbA1c
Detection equipment	Mass spectrometer, spectrophotometers, ELISA readers providing raw data which is not readily readable and understandable by the user (e.g. peaks, OD).	McFarland bacteria density testing
Others	Foetal calf serum, cell culture media, fixation solution, mounting media, buffers (e.g. PBS), chemicals (e.g. sulphuric acid, formol, water)	

RULE 5

The following devices are classified as class A:

(a) Products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures relating to a specific examination

RATIONALE

Rule 5a applies to general laboratory products like pipettes, stain powders, glass microscope slides, centrifuges, pipette tips or instrument liquid collection containers, buffers which usually do not fall under the definition of an IVD medical device. However, as specified in Regulation (EU) 2017/746 Article 1 (3a) 'This regulation does not apply to (a) products for general laboratory use (...), unless such products, in view (...) are specifically intended by their manufacturer to be used for *in vitro* diagnostic examinations.'

As a consequence, if such products are specifically intended by the manufacturer to be used for *in vitro* diagnostic examinations, then they are considered as IVDs and are captured by rule 5.

'Accessory for an *in vitro* diagnostic medical device' as defined under Regulation (EU) 2017/746 article 2 (4), 'means an article which, whilst not being itself an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the *in vitro* diagnostic medical device(s) in terms of its/their intended purpose(s)'.

Whilst not being an IVD in themselves, accessories are to be used in conjunction with a specific IVD. They possess *one or more specific characteristics* to specifically enable an IVD to be used in accordance with its intended purpose or to assist the medical functionality of the IVD. Accessories are mentioned in rule 5 (a) in combination with the attribute '*accessories which possess no critical characteristics*'. This emphasizes that such products can negatively influence the benefit-risk ratio of the entire *in vitro* diagnostic medical device.

EXAMPLES (non-exhaustive)

- General microbiological culture media containing selecting agents, antimicrobial chromogenic agents, chemical indicators for colour differentiation.
- Solutions like cleaners, buffer solutions, lysing solutions, diluents specified for use with an IVD.
- Pipette with a specific fixed one volume specifically intended for a particular IVD test with specified human sample, e.g. blood coagulation pipettes with automatic timing (Accessory of coagulometer).
- General staining reagents like hematoxylin, eosin, pap and grams iodine.
- Kits for Isolation and purification of nucleic acids from human specimens.
- Library Prep reagents for preparation of DNA for downstream analysis by NGS sequencing.
- Nucleic acid quantitation kits.
- General reagents (not assay specific) used with a Class A instrument, e.g. general sequencing consumable reagents used with a sequencer.

If they are specifically intended for IVD use they are IVDs under rule 5 but class A

IVDD Guidance RUO MEDDEV. 2.14/2 rev.1

- Therefore once a medical device is intended by the manufacturer to be used for medical purposes it must either fall under the category of a product undergoing performance evaluation for the purpose of CE marking or be a product which is CE marked.
- **‘For research use only’ products do not have an intended medical purpose.**
- When a medical purpose has been established based on sufficient and broadly agreed upon scientific, diagnostic and clinical evidence, then the product must comply with the requirements of the Directive before the manufacturer can place it on the market with an intended IVD use.

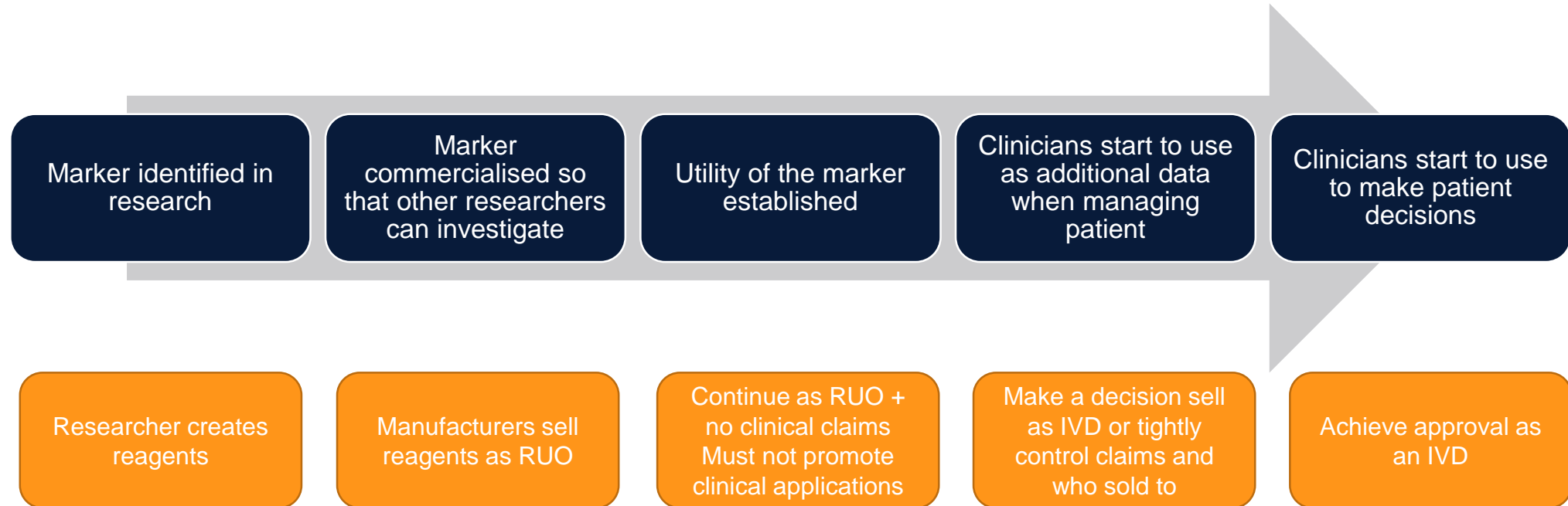
Examples

- **RUO products used for Basic Research:**
- **RUO products used in Pharmaceutical Research:**
- **RUO products used for a better identification and quantification of individual chemical substances or ligands in biological specimens:**
- **In house manufacturing of so called “home brew kits” by a legal entity for the purpose of research:**

Novel Devices

- **If you are developing a device the first thing you need to think,**
 - What is the intended purpose now
 - What are my aspirations for future intended purpose?
 - Do you intend it to become an IVD or just a research tool?

Novel Analyte – e.g. New biomarker for cancer



- What is your intended purpose and does it meet the IVDR definition?
- Who do you sell it to?
- What claims do you make when you sell it?



**DANGER
ZONE**

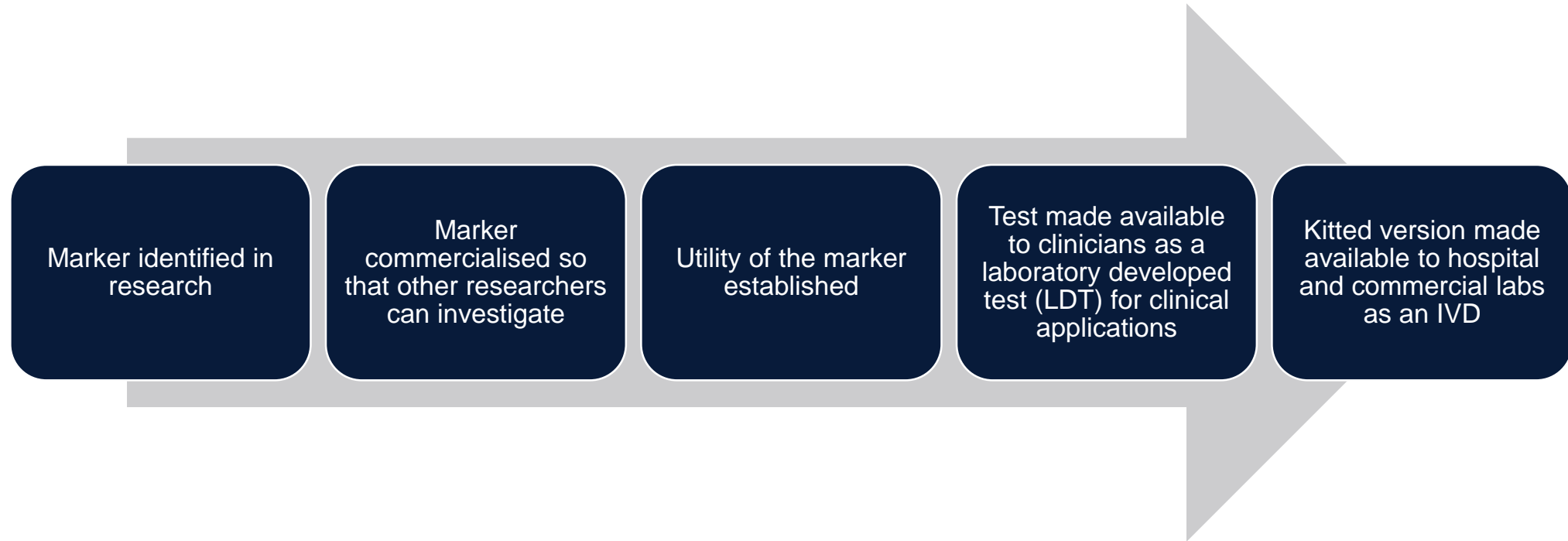
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Manufacturers Responsibilities

Manufacturer

- Means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;
- Previously some countries allowed piggybacking off of OEM CE certificates where the manufacturer only held a Summary Technical Documentation (STED) these OBL/ private label arrangement are no longer accepted
- Manufacturers must:
 - Hold the full technical documentation under the manufacturers QMS
 - Responsible for design, design changes and manufacturing
 - Make arrangements for PMS/PMPF and vigilance activities with the OEM
 - Draw up a Declaration of Conformity
 - OEMs likely to be audited by the manufacturers Notified Body and are eligible for unannounced audits, on behalf of the legal manufacturer and access by the NB should be described in the contract

Alternative routes to market **in the US** What about EU?



More to follow in the next webinar!!!!



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Thank you for your attention

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