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What you need to know about the new European IVD Regulation

Stefan Burde
October 8, 2015

What you need to know about the new European IVD Regulation

- What is it?
- Why do we need it?
- When is it coming?
- What are the major changes?
  - Risk-based IVD Device Classification Approach
  - Routes to Conformity
  - Clinical Expectations
  - Responsibilities of the Manufacturer, Importer and Distributors and In-house Manufacture

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10/5/2015

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Caution

- The new regulations are draft the principles have now been agreed but the Annexes are subject to minor changes
- Further details will be added later pre and post application through implementing and delegating legislation

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Why do we need it?

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Impetus for the changes

- Discovery of a 16 year fraud in PIP breast implants using low quality “industrial grade” silicon oil
- Stress test performed by EU Commission
- Determine that changes were needed to improve early detection and prevent this type if incident
- Other high profile vigilance cases with hips, pelvic floor meshes, pacemaker leads, etc.

Outcome

- Short term changes proposed to the system:
  - Increased market surveillance
  - Additional unannounced visits on top of regular audits
  - Identify a person who is responsible for regulatory compliance

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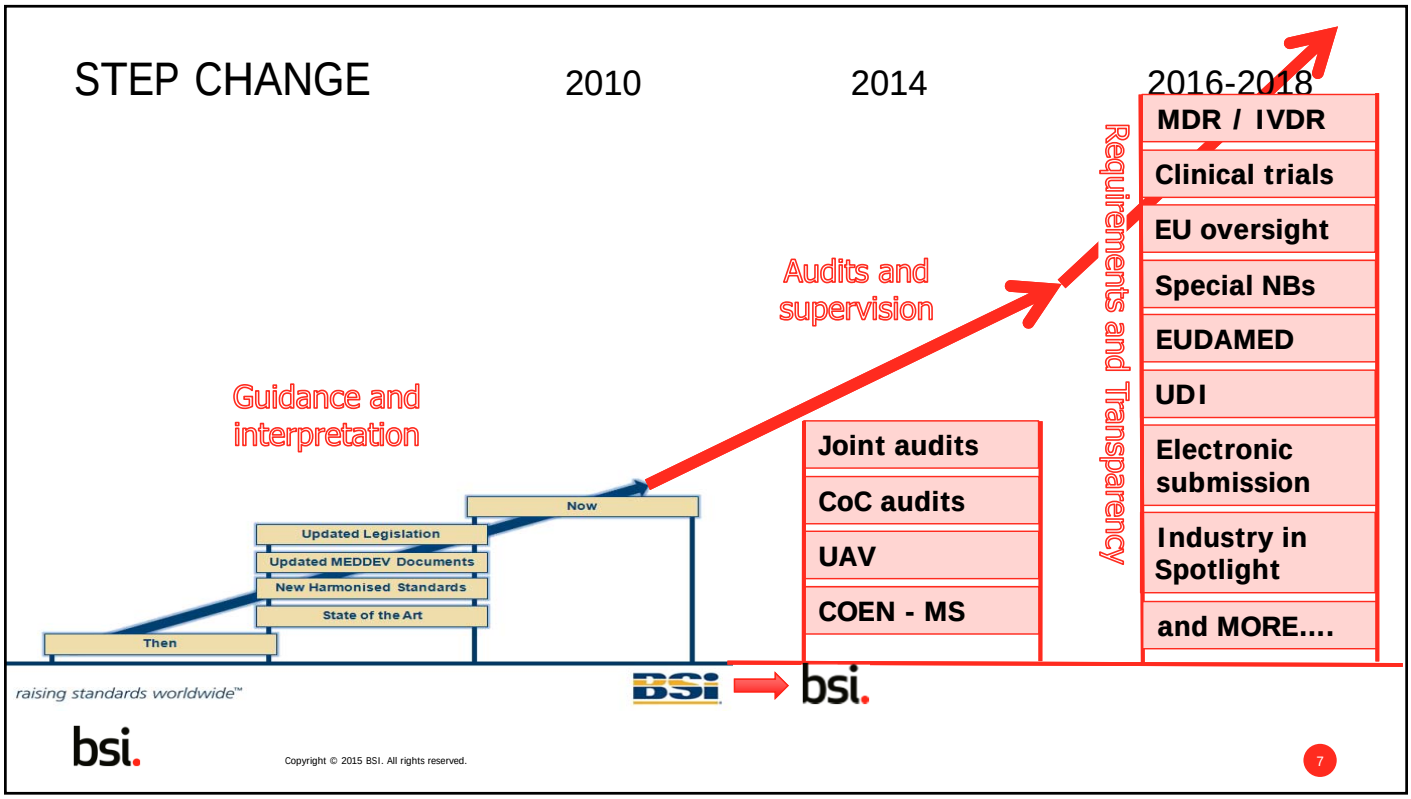
STEP CHANGE
2010
2014
2016-2018
Requirements and Transparency
Audits and supervision
Guidance and interpretation
Then
State of the Art
New Harmonised Standards
Updated MEDDEV Documents
Updated Legislation
Now
Joint audits
CoC audits
UAV
COEN - MS
MDR / IVDR
Clinical trials
EU oversight
Special NBs
EUDAMED
UDI
Electronic submission
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Advantages to the proposed changes

- Appropriate regulation of the entire IVD market
  - Current directive focuses on a limited number of devices of particular concern at the time of issue
  - New risk-based classification scheme captures the majority of devices, and is applicable to new devices that may come to market in the future
  - The level of regulatory scrutiny is commensurate with the relative risk of the device
- Consistent application
  - Under the current directive, each member state has implemented the directive slightly differently into national law
  - Raises concern about unequal competition

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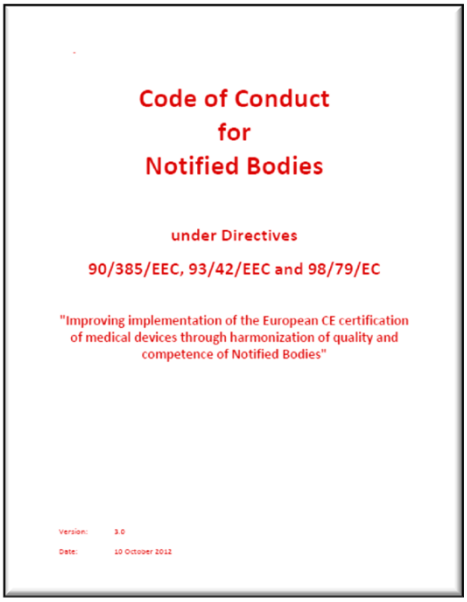
We need to establish a level playing field

Notified Body Code of Conduct

- Mandatory to sign for TEAM-NB members
- Current version is available on website www.team-nb.org
- New version to be approved soon
  - Frequency of UAV
  - Focus of UAV



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What is it?

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IVD directive will become a regulation

What's the difference

- A Directive is agreed by the European Parliament and Council and *directs* member states to pass national legislation to implement the directive
- A Regulation is a law agreed by the European Parliament and Council that takes effect directly in all member states

Impact of becoming a regulation

- The regulation is intended to result in more consistent application i.e. same text throughout EU
- Direct entry into force
- No Transposition period as it doesn't need transposing into Member State law
- There will be a transition period of 5 years
- The regulation identifies areas which can be updated in the future using additional implementing acts according to Article 84(3)

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Structure of the IVDR

Chapters 10
Articles 90
Annexes 14

Annex I
General Safety and Performance Requirements
- Equivalent to the current essential requirement
- Broadly similar with additional clarification
- New sections for software and requirements for use with mobile platforms
- Requirements for self tests are extended to include near patient testing

Annex II
Technical documentation
- Significantly more detail regarding the expectations for technical documentation

Annex III Declaration of Conformity
Annex IV CE marking
Annex V Registration and UDI
Annex VI Requirements for Notified Bodies
Annex VII Classification
Annex VIII Conformity Assessment based on Full QA or Design Examination
Annex IX Conformity Assessment based on Type Examination
Annex X Conformity Assessment based on Production QA
Annex XI Notified Bodies Certificate content
Annex XII Clinical Evidence and Post Market Follow up
Annex XIII Interventional Clinical Performance Studies
Annex XIV Correlation table

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More detailed & more prescriptive; consistent with the proposed Medical Device Regulation

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When is it coming?

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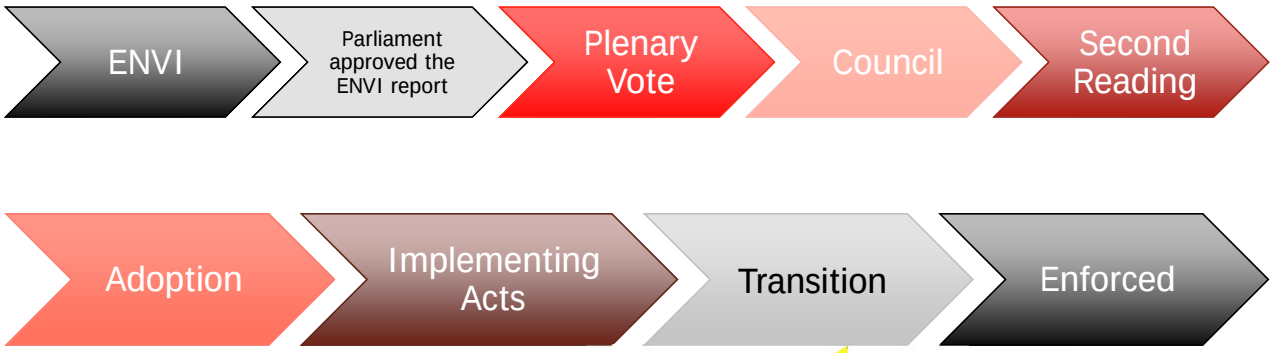
Timeline



IVDR 2016

5 Years

IVDR must be applied 2021

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Process

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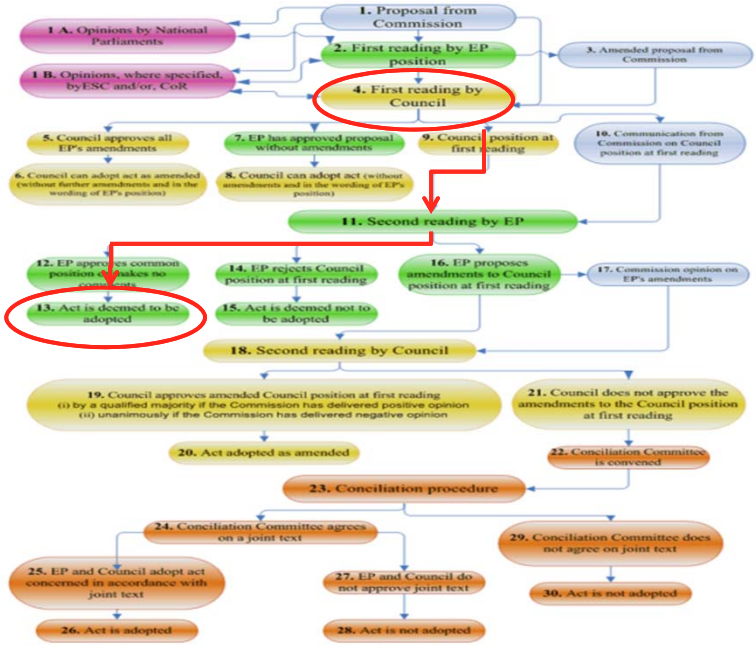

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Process

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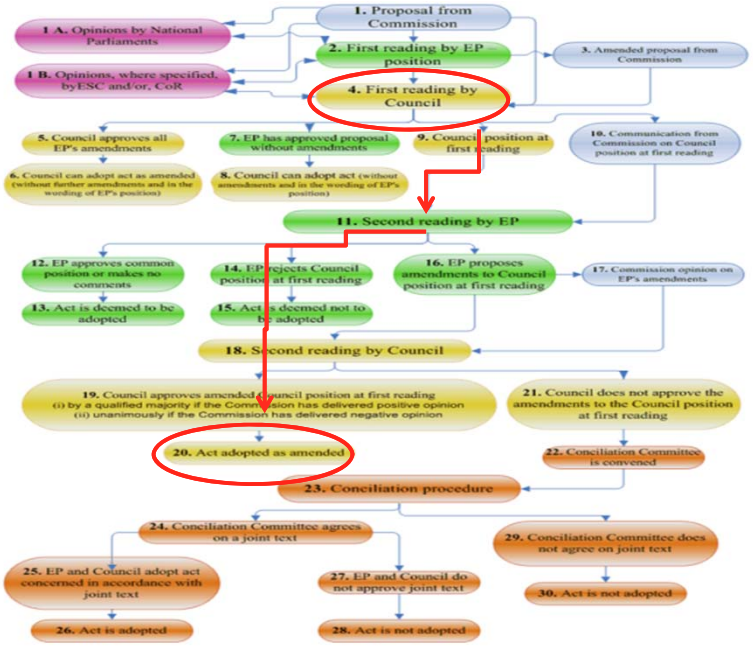

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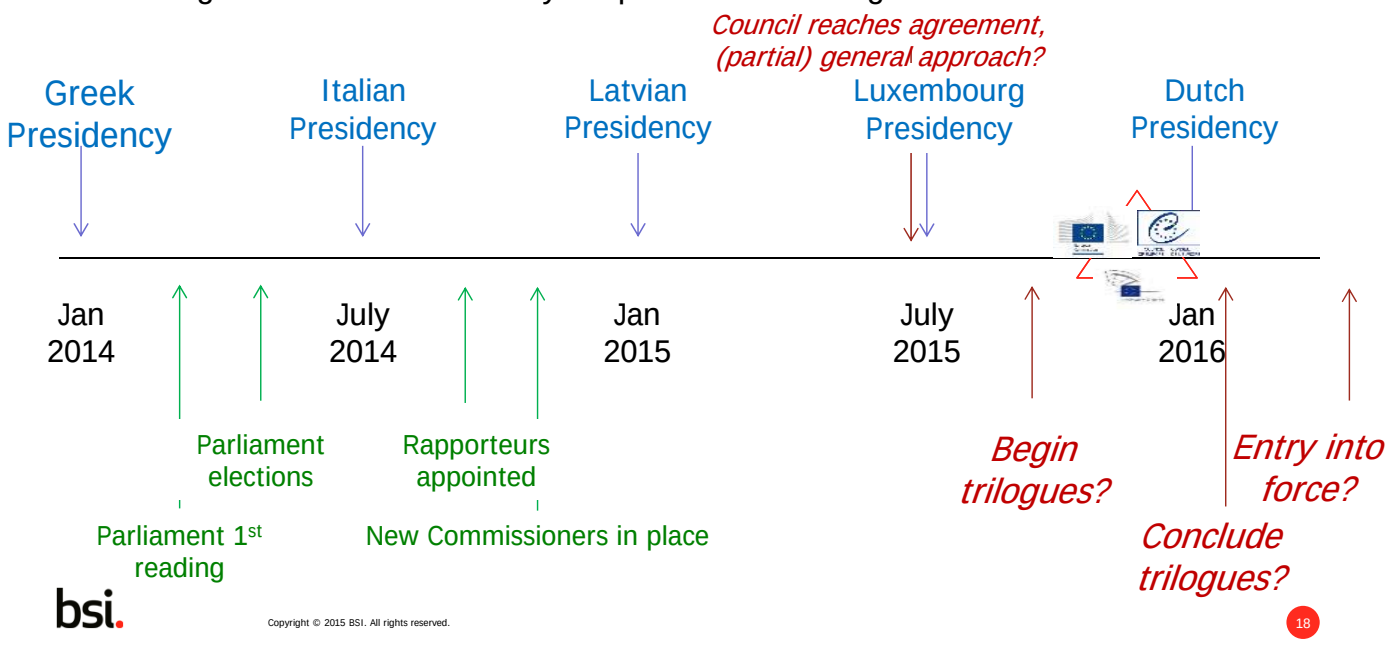
Timeline – Realistic Expectations: (slide from MHRA)

Plan: 6 negotiation rounds and early adoption in 2nd reading



Timeline – Realistic Expectations: (slide from MHRA)

Plan: 6 n[illegible] 2nd reading

Greek Presidency

Jan 2014

Dutch [illegible]esidency

Jan 2016

Tentative schedule for Trilogues and Adoption

5 October	CoRePer formal Council Full Agreement
Trilogues:	
13 October	Chapters I and II (without Art 15 – reprocessing)
26/29 October	Article 15 and many other Chapters and Articles
10 November	Mainly IVDs
18 November	Pre-market scrutiny and management of Notified Bodies
3 December	Resolve outstanding issues and finalise agreement

Rapid 2nd Reading in Parliament (if all things agreed)

Adoption of MDR and IVDDR hopefully early during 2016 in Dutch Presidency

Entry into force?

Parliam[illegible] read

[illegible]onclude [illegible]rilogues?

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What are the major changes? What is different in the latest draft published June 2015?

Risk-based classification approach

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Change to scope of IVDR through MDR

New views from Council

- 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific ~~*direct or indirect*~~ medical purposes of:
  - diagnosis, prevention, monitoring, *prediction, prognosis,* treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
  - investigation, replacement or modification of the anatomy or of a physiological process or state,
  - investigation, replacement or modification of the anatomy or of a physiological process or state,
  - disinfection or sterilisation of any of the above-mentioned products,
  - *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations*,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Impact
Tests to predict the likelihood patients will develop a disease will be included, Life style tests for example tests to suggest dietary changes for health reasons will only be included if there is a clear medical purpose

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Scope

'*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, 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:

- concerning a physiological or pathological *process or* state;
- concerning a congenital abnormality *(previous draft stated physical or mental impairment)*
- concerning the predisposition to a medical condition or a disease;
- to determine the safety and compatibility with potential recipients;
- to predict treatment response or reactions;
- to define or monitor therapeutic measures.

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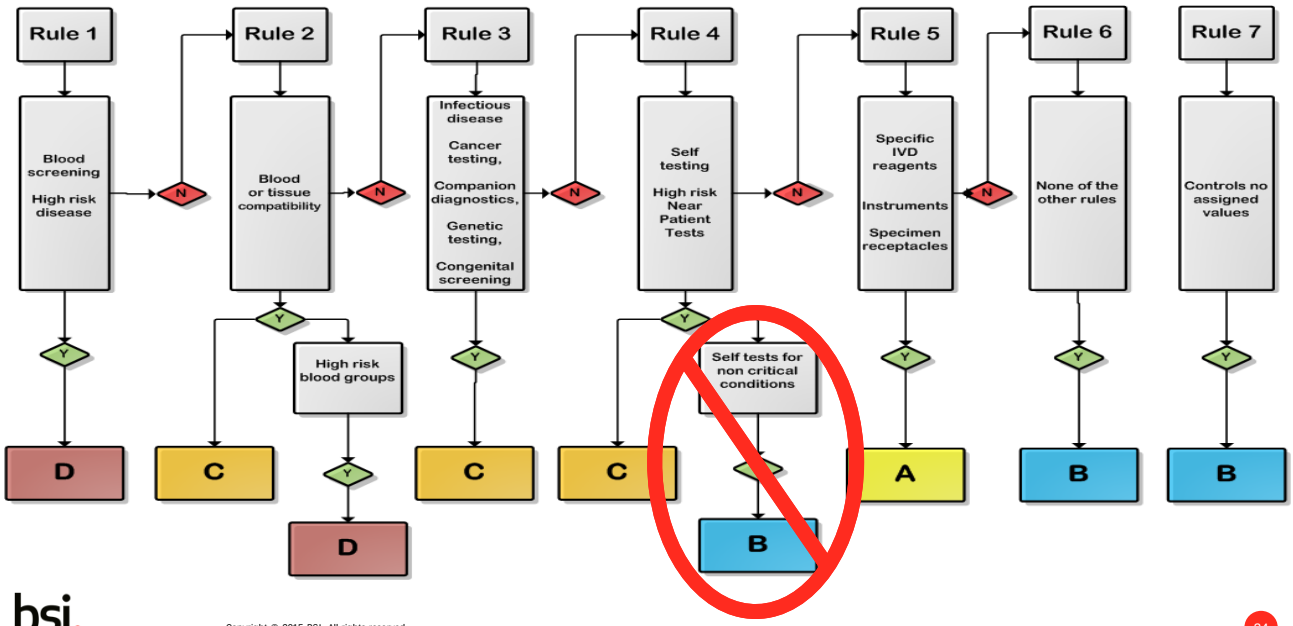
IVD Classification

Application of the classification rules shall be governed by the intended purpose***, novelty, complexity and inherent risk*** of the devices.



Classification

New views from Council

Class D (Blood screening)

- Devices intended to be used to detect the presence of, or exposure to,
  - a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation *or cell administration*.
  - a transmissible agent that causes a life-threatening disease with a high or ~~currently undefined~~ *suspected high* risk of propagation
  - *Devices intended to be used to determine the infectious load of a life-threatening disease where its monitoring is critical in the process of patient management.*
  - *All assays for the clinical diagnosis and monitoring of infection by HIV 1/2, Hepatitis C virus, Hepatitis B virus and HTLV I/II devices should be classified as class D. Assays for the clinical diagnosis of Hepatitis B virus are taken to include the following infectious disease markers: Hepatitis B surface antigen (HBsAg), Hepatitis B core total antibodies (anti-HBc total) and Hepatitis B virus nucleic acid detection (HBV NAT).*
- Blood grouping ABO, Rhesus *(including RHW1)*, Kell, Kidd and Duffy systems

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Classification

Class C

Devices intended for

a. detecting the presence of, or exposure to, a sexually transmitted agent;
b. detecting the presence in cerebrospinal fluid or blood of an infectious agent *without* a *high or suspected high* risk of propagation;
c. detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus being tested, or to the individual's offspring;
d. pre-natal screening of women in order to determine their immune status towards transmissible agents;
e. determining infective disease status or immune status, if there is a risk that an erroneous result would lead to a patient management decision resulting in an imminent life-threatening situation for the patient or for the patient's offspring;

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Classification

Class C (Continued)

f. Devices intended to be used as companion diagnostics*; or

fa Devices intended to be used for disease staging ~~*or prognosis*~~ *if there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring*

fb Devices intended to be used in screening diagnosis *or staging* of cancer.

g. human genetic testing;

h. monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a~~n imminent~~ life-threatening situation for the patient or for the patient's offspring;

i. management of patients suffering from a life-threatening ~~infectious~~ disease or condition;

j. screening for congenital disorders in the foetus ~~*or embryo*~~

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Classification

Class C (Continued)

k. screening for congenital disorders in new-born where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.

- Devices intended for self-testing are classified as class C~~, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B~~.

- devices intended for blood gases and blood glucose determinations for near patient testing are class C. Other devices that are intended for near-patient testing shall be classified in their own right.

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Companion Diagnostics – New v Old Definition

New Proposal from EU Council of Companion Diagnostics

- 'companion diagnostic' means a device which is essential for the safe and effective use of a corresponding medicinal product to:
  - identify patients who are most likely to benefit from the medicinal product, or;
  - identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with the medicinal product, or;
  - monitor response to treatment by the medicinal product for the purpose of adjusting treatment to achieve improved safety or effectiveness

FDA CDx Guidance on Companion Diagnostics

- An *IVD companion diagnostic device* is an IVD device that provides information that is essential for the safe and effective use of a corresponding therapeutic product…
- An IVD companion diagnostic device could be essential for the safe and effective use of a corresponding therapeutic product to:
- Identify patients who are most likely to benefit from the therapeutic product
- Identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with the therapeutic product
- Monitor response to treatment with the therapeutic product for the purpose of adjusting treatment (e.g., schedule, dose, discontinuation) to achieve improved safety or effectiveness
- Identify patients in the population for whom the therapeutic product has been adequately studied, and found safe and effective, i.e., there is insufficient information about the safety and effectiveness of the therapeutic product in any other population

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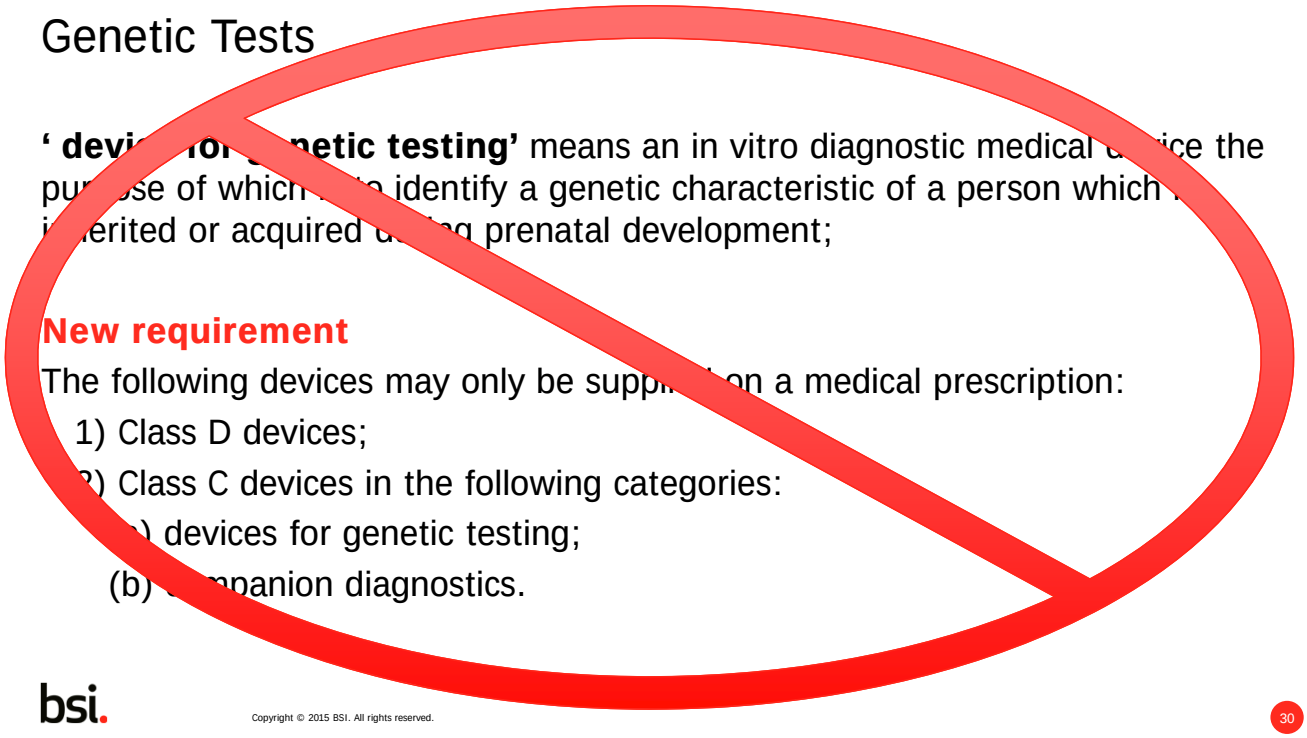
Genetic Tests

‘ devi ... for ... netic testing’ means an in vitro diagnostic medical d... ice the pu...se of which ... identify a genetic characteristic of a person which ... inherited or acquired d... prenatal development;

New requirement

The following devices may only be suppl... on a medical prescription:

1) Class D devices;
2) Class C devices in the following categories:
   (a) devices for genetic testing;
   (b) companion diagnostics.



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Classification

Class B

- Any IVD not listed under Classes D, C or A.
- Controls without an assigned value.

Class A

- *Products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions* intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures related to a specific examination
- Instruments intended specifically for use in IVD procedures.
- Specimen receptacles.

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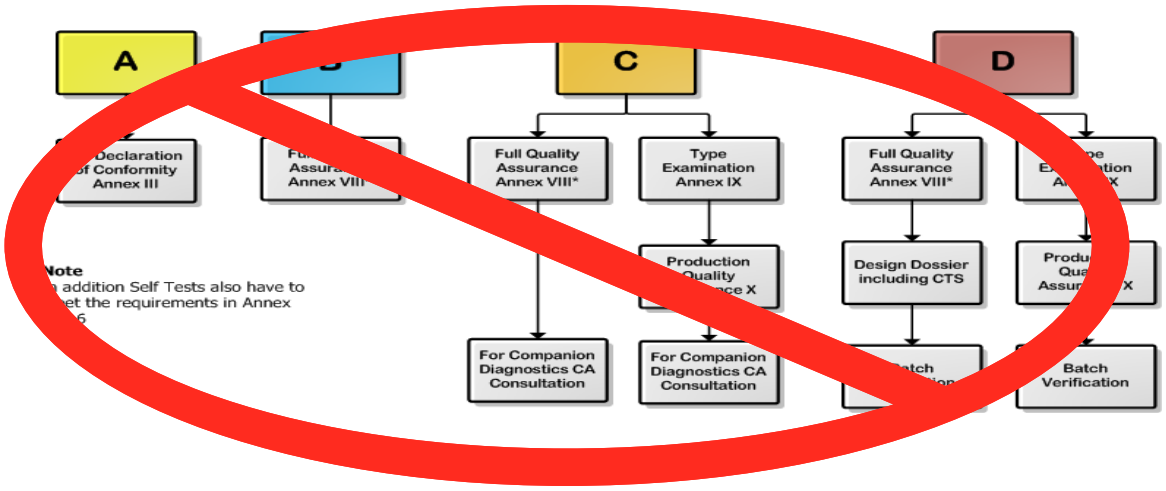
Routes to conformity

Conformity Assessment Routes



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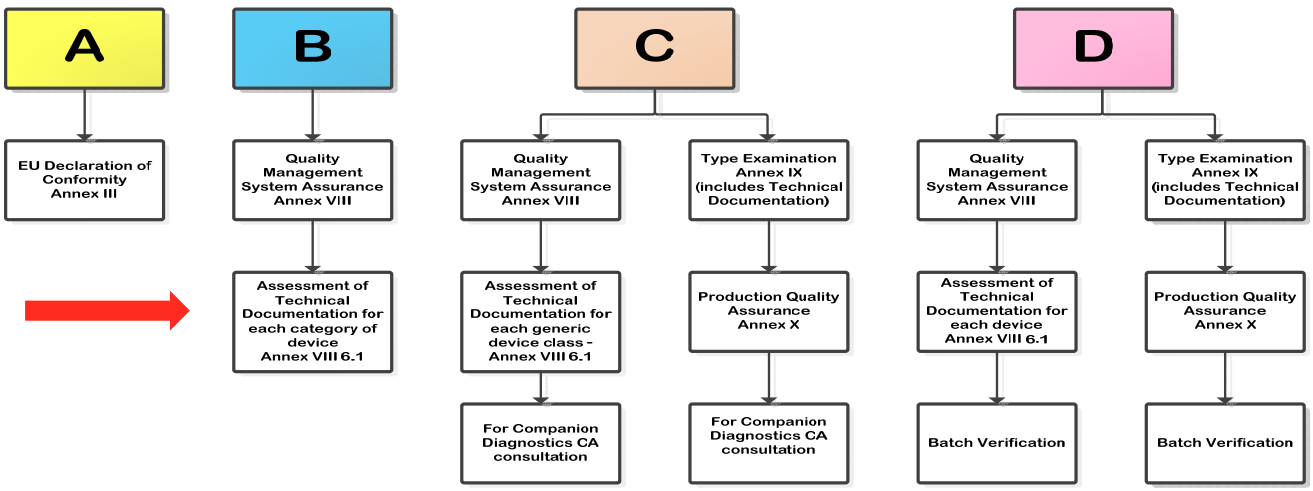
Conformity Assessment Routes



All technical file reviews will be in depth
<u>BUT</u> there is more sampling for D v C v *B*

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Sampling

Class D
- Assessment of the technical documentation

Class C
- Assessment of the technical documentation of at least one device representative per generic device group

Class B
- Assessment of the technical documentation of at least one representative device *for each category of devices*

Class A
- Notified Body not required unless sterile

In choosing representative sample(s) the notified body shall take into account the guidance developed and published by the MDCG
- in particular the novelty of the technology,
- the potential impact on the patient and practice of medicine,
- similarities in design, technology, manufacturing and sterilisation methods, the
- intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation.
- The notified body shall document its rationale for the sample(s) taken.

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Additional Scrutiny for Class D devices

Pre Certification

- As part of the conformity assessment a reference laboratory will test the device to the Common Specification with specific focus on sensitivity. The notified body must take this into consideration the Reference lab has 60 days to respond

Post certification

- The NB informs the Commission of all Class D certificates
- A Competent Authority or the Commission can select a file for review following concerns outlined in the IVDR
- The Commission will create an electronic document exchange system with the Notified Body

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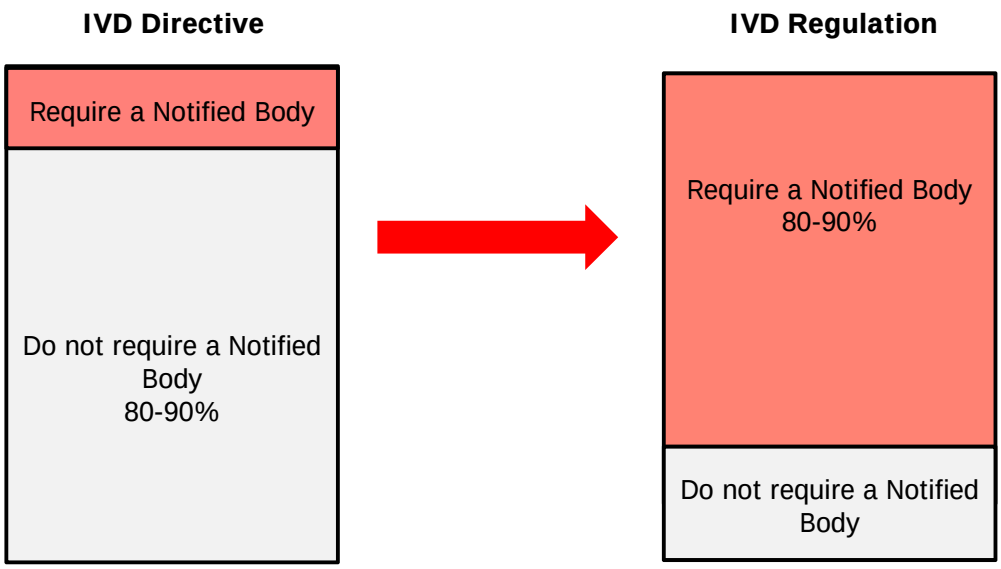
Quantum Leap



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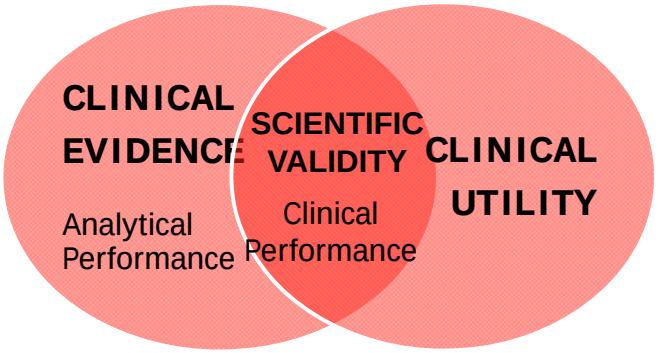
Clinical Expectations

Clinical Requirements

- Increased expectation for clinical requirements
- Clinical evidence is to be kept up to date during the life time of the device

The GHTF documents now in the IMDRF archive best guidance

- Clinical Performance Studies for In Vitro Diagnostic Medical Devices
- Clinical Evidence for IVD Medical Devices – Key Definitions and Concepts
- Clinical Evidence for IVD Medical Devices – Scientific Validity Determination and Performance Evaluation



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Definitions

These changes have a big impact

(28) 'clinical evidence' means the ***clinical data and performance evaluation results pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used*** as intended by the manufacturer

(33) 'performance study' means a study undertaken to establish or confirm the clinical performance of a device;

(34) 'clinical performance study ***plan*** ' means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and recordkeeping of the clinical performance study;

(35) 'performance evaluation' means the assessment and analysis of data to establish or verify the ***scientific validity***, the analytical and, where applicable, the clinical performance of a device;

(58) 'common specifications' means a document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligations applicable to a device, process or system. [previously called common *technical* specification]

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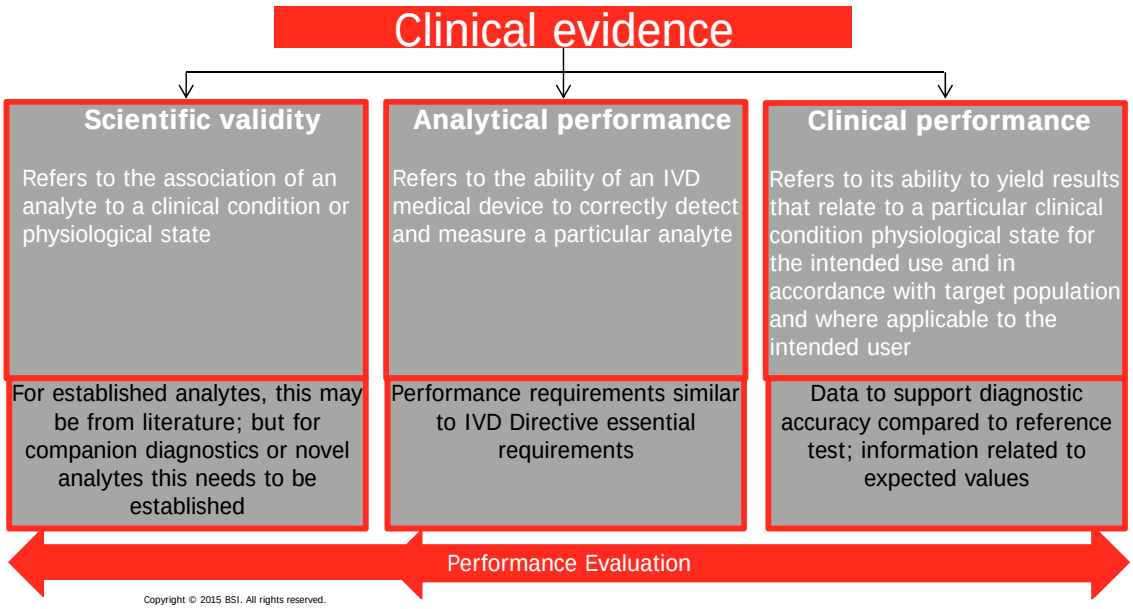
Clinical evidence



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Performance evaluation and performance studies

Chapter VI ~~Clinical evidence~~ *Performance evaluation and performance studies*

Article 47

2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer *and be based on a continuous process of performance evaluation, following a performance evaluation plan*.

6. The *performance evaluation* and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's *post-market performance follow-up plan, as part of the* post-market surveillance plan referred to in Article 8(7).

The performance evaluation report for devices classified as class C and D shall be updated when necessary, but at least annually with these data. The summary of safety and performance referred to in Article 24(1) shall be updated as soon as possible, where necessary.

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Performance Studies

Article 48

General requirements regarding performance studies

1. *Performance* studies shall be subject to *the provisions of Articles 48 to 58 of* this Regulation if they are conducted *under* one or more of the following *conditions*:

(a) *where invasive sample taking is done only for the purpose of the performance study*

(b) *where it concerns an interventional clinical performance study as defined in Article 2(37)*;

(c) *where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies;*

(d) in case of performance studies involving companion diagnostics.

2. *Performance* studies shall be performed in circumstances similar to the normal conditions of use of the device.

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Responsibilities of the manufacturer, importer and distributers plus in-house manufacture

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Economic Operators

Manufacturer

means the natural or legal person *with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under that person's own name, regardless of whether those operations are carried out by that person or on that person's behalf by a third party. The obligations of this Regulation to be met by* manufactures *also apply to natural or legal persons who assemble, package, process,* fully refurbish *or label one or more ready-made products and/or assign to them their intended purpose as devices with a view to their being placed on the market* under *that person's own* name or trademark.

Importer

means any natural or legal person established within the Union who places a device from a third country on the Union market;

Distributor

means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;

Economic operators

means the manufacturer, the authorised representative, the importer and the distributor;

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Control of the Supply Chain

- Increase expectation for virtual manufacturers and OBL to hold or have quick access to technical documentation during audits
- Notified bodies can now audit crucial suppliers as well as significant subcontractors including unannounced visits
- Changes to contracts will be required

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Increased Control of the Supply Chain

- Regulatory roles and requirements of
  - Importers
  - Distributers
  - Authorised Representatives

These include

- Registration and keeping data up to date
- Mandate with the authorised representative
- Roles in vigilance and recall
- Required to have a Person responsible for regulatory compliance
- Manufacturers now have to have liability insurance but importers required to check this is adequate or take out their own

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Person Responsible for Regulatory Compliance

- Manufacturers shall have available within their organisation at least one person ***responsible for regulatory compliance*** who possesses ***the requisite expertise*** in the field of *in vitro* diagnostic medical devices.
- This will include:
  - a degree or equivalent in natural sciences, medicine, pharmacy, engineering
  - or 3 years of professional experience in regulatory affairs or in QMS relating to IVDs
- The person responsible for regulatory compliance is responsible for ensuring:
  - that the conformity of the devices is appropriately assessed before a batch is released;
  - that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
  - that vigilance requirements have been fulfilled.
  - for performance evaluation for interventional studies
  - If compliance is share between more than one person responsibilities will be defined in writing
- This person should suffer no disadvantage by performing their role
- Authorised representatives will also be required to have a person responsible for regulatory compliance within their organisation.

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In-house Exemption for Cl

- If Class D dev are manufactured and used within a single health institution, are *exempt from* the requ s of this Regulation, *with the exception of vigilance requirements a neral safety perf ance req ments where the following conditions are met:*
  - *(a) the recipient pati patient group's specific needs cannot be met by an available CE-marked dev as such, and therefore, either a CE ked device needs to be modified or a new device needs to be manufactured*
  - *(b) the health institution is accr to ISO standard 15189 quality management system, or any other equi ent recognised standard;*

- *The Commission shall verify that the devices hat list are eligible for exemption in accordance w the requirements under this paragraph.*

  The information on exempt devices shall be made publi

  Member States shall retain the right to restrict the in-house m facture and use of any specific be in-vitro diagnostic device in relation to aspects that are not cove by this Regulation, and y a make the manufacture and use of the devices concerned subject to her safety requ ments. In su ases, Member States shall inform the Commission and the other Me State cordingly.

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In-House Manufacture (equivalent to LDT)

With the exception of *the relevant general safety and performance requirements set out in Annex I*, the requirements of this Regulation shall not apply to Devices manufactured and used only within health institutions *established in the Union*, provided *that the following conditions are met:*

(aa) the device is not transferred to another legal entity

(a) manufacture and use *of the device* occur under *appropriate* quality management system

(b) the *laboratory of the* health institution is compliant with standard EN ISO 15189 *and where applicable national provisions, including national provisions regarding accreditation*.

(c) *the health institution establishes in its documentation that it has given due consideration as to whether the target patient group's specific needs cannot be met or*

cannot be met at the appropriate level of performance by an equivalent device

available on the market;

(d) *the health institution provides information on annual basis on the use of such devices*

to their competent authority, which shall include a justification of their manufacturing, modification and use;

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In-House Manufacture continued

(e) the health institution draws up a declaration, that it shall make publicly available including:

- the name and address of the manufacturing health institution;

- the details necessary to identify the devices;

- a declaration that the devices meet the general safety and performance requirements set out in Annex I of this Regulation and, where applicable, information on which requirements are not fully met with reasoned justification,

(f) as regards devices classified as class C and D in accordance with the rules set out in Annex VII, the health institution draws up documentation, allowing an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I of this Regulation are met; Member States may apply this provision also to devices classified as class A and B in accordance with the rules set out in Annex VII;

(g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in the previous subparagraph, and

(h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

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Distance sales

- A device offered by means of “information society services” this includes the internet
- A kit does not have to be sold in EU the IVDR applies if it has been used to test EU citizens the IVDR states if “a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.”
- Competent authorities can ask the legally responsible manufacturer or body offering the device or providing a service to provide a copy of their EU declaration of conformity of the device
- If a Member State has grounds for concern based on the of protection of public health, the provider will be required to cease its activity.

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Emerging Pathogens

- In the case of urgent or unmet medical needs for patients, such as emerging pathogens and rare diseases, single health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, within a non-commercial and flexible framework, specific needs which cannot be met by an available CE-marked device.
- However, devices which are manufactured within non-health-institution laboratories and put into service without being placed onto the market should be subject to this Regulation.

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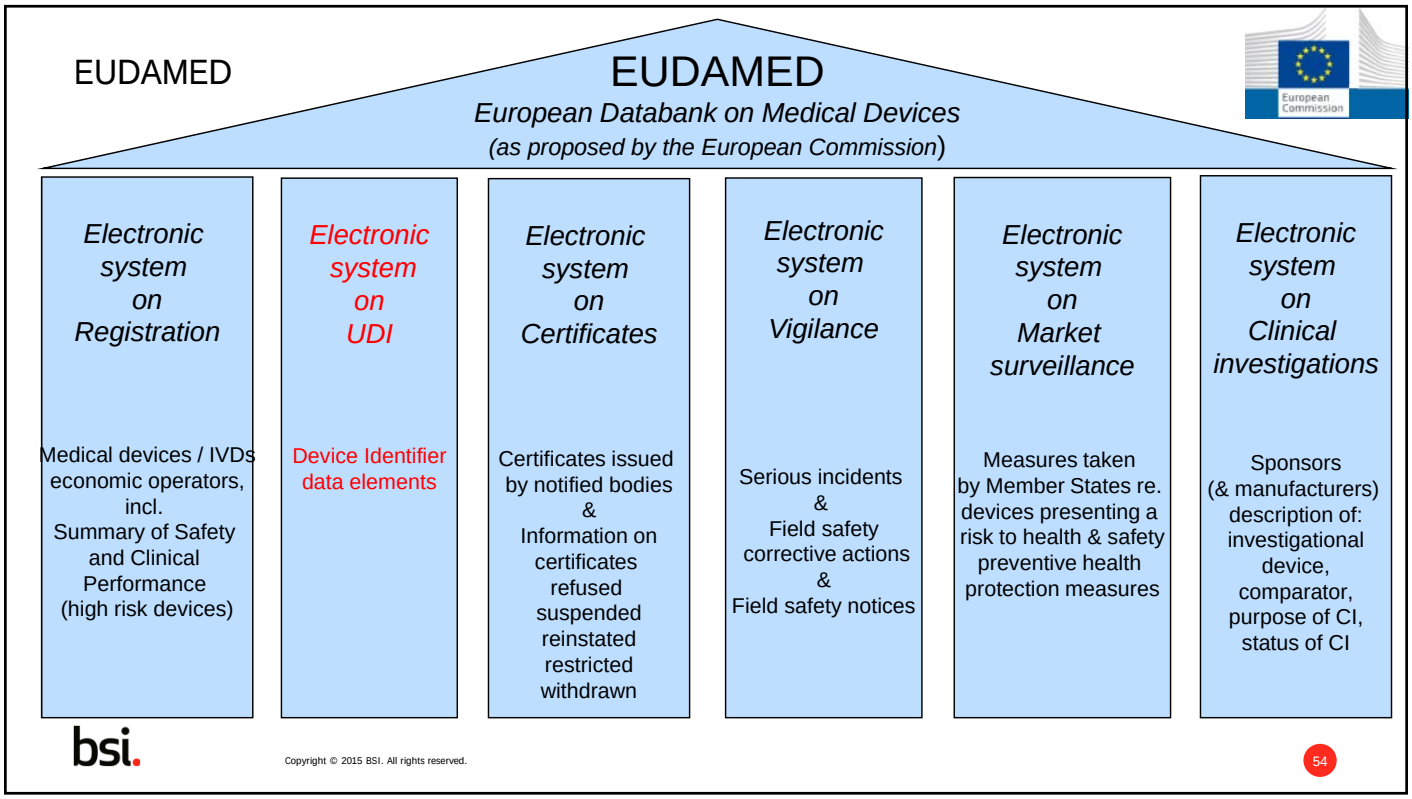
EUDAMED
EUDAMED
European Databank on Medical Devices
(as proposed by the European Commission)
European Commission
Electronic system on Registration
Medical devices / IVDs economic operators, incl. Summary of Safety and Clinical Performance (high risk devices)
Electronic system on UDI
Device Identifier data elements
Electronic system on Certificates
Certificates issued by notified bodies & Information on certificates refused suspended reinstated restricted withdrawn
Electronic system on Vigilance
Serious incidents & Field safety corrective actions & Field safety notices
Electronic system on Market surveillance
Measures taken by Member States re. devices presenting a risk to health & safety preventive health protection measures
Electronic system on Clinical investigations
Sponsors (& manufacturers) description of: investigational device, comparator, purpose of CI, status of CI
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UDI

Bar-coding
for every Medical Device

(01) 1 4987578 12345 0 (17) 251210 (10) ABC1234

DI
Device Information
- Company
- Product ID

PI
Production Information
-Life
-Serial or Lot Information

UDID
Database
For DI part Only

DI
-Company Name
Address
-Product Name
.
-GMDN
-code
-term
.
. etc

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Unique Device Identifier

- The Commission shall be empowered to adopt delegated acts in accordance with Article 85:
- (a) determining the devices, categories or groups of devices, whose identification shall be based on the UDI system, … and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be gradual, starting with devices falling in the highest risk class;
- (b) specifying the data to be included in the production identifier which, following a risk-based approach, may vary depending on the risk class of the device;
- (c) defining the obligations of economic operators, of health institutions and of professional users, in particular regarding allocation of the numeric or alphanumeric characters, placement of the UDI on the label, storage of information in the electronic system on UDI, and use of the UDI in documentation and reporting related to the device provided for in this Regulation;
- (d) amending or supplementing the list of information … in the light of technical progress.

- UDI will ultimately be required
  - Development of a UDI system is lagging behind US efforts
  - The European Commission intends to make the system *as similar as possible* to the US system.
  - For the time being, following US rules should prepare manufacturers adequately for European roll-out

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Final Summary

- This is happening in the home stretch now but recent changes have been significant
- Remember there is no grandfathering
- Requirements and expectations are increasing
- Keep up to speed, there will fewer changes now primarily to the Annexes
- Understand the impact to your organisation
- Talk to your notified body about their plans for designation and resource
- Classify your devices
- Look at the clinical data you have, is it enough how can you get what you need?
- Discuss at management reviews

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Quick Rundown of Selected Changes in the New Draft Published in June 2015

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New Views From Council

- Chapter I - Scope and definitions
  - Added organ, blood and tissue donations
  - Accessory defined more strictly (specifically enable ... intended purpose)
  - Clinical evidence redefined
  - Companion diagnostic redefined
- Chapter II - Operators, reprocessing, CE marking, free movement
  - Solution found to keep health institutions free from CE marking BUT will be transparent and justified
  - Authorised Representative and Importer legally liable for defective devices
  - Prescribed requirements for QMS
  - Person responsible for regulatory compliance activities may be outsourced by small businesses (< 50 employees & < EUR 10M revenue)

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New Views From Council

- Chapter III – Identification, registration, summary of safety and performance, European databank
  - Electronic registration of manufacturer and Authorised Representative
  - Single identification number – to appear on labels.
- Chapter IV – Notified bodies
  - NB shall make available and submit upon request, all relevant documentation, including the manufacturer's documentation to the CA. NB will have to retain copies of DDs and TFs
- Chapter V – Classification and conformity assessment
  - Design examination Class D BUT in depth Technical File review for B. C and D introduced, this will be similar to a current design dossier review, sampling based on classification using GMDN and NBOG codes to determine the frequency
  - Detailed change control, reviews before and after change

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New Views From Council

- Chapter VI – Performance evaluation and performance studies
  - Scientific validity, analytical and clinical performance required to demonstrate conformity
  - Continuous evaluation; post-market performance follow-up plan
  - Electronic registration of studies bearing risks to subjects
- Chapter VII – Post-market surveillance, vigilance and market surveillance
  - Post-market surveillance plan requirements
  - Periodic safety update requirement – at least annually plus trend reporting
  - Annual surveillance plan from member states, including inspections and UAV at economic operators

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Useful links

- Current IVDD
  - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20090807:EN:PDF
- European Commission Recommendation on Unannounced Audits
  - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:253:0027:0035:EN:PDF
- Index of MEDDEV Guidance Documents
  - http://ec.europa.eu/growth/sectors/medical-devices/guidance/index_en.htm
- European Commission Medical Device Landing Page
  - http://ec.europa.eu/growth/sectors/medical-devices/index_en.htm
- Draft IVDR
  - http://data.consilium.europa.eu/doc/document/ST-9770-2015-INIT/en/pdf - Articles
  - http://data.consilium.europa.eu/doc/document/ST-9770-2015-ADD-1/en/pdf - Annexes
- GHTF Archives
  - http://www.imdrf.org/ghtf/ghtf-archived-docs.asp
- BSI IVD Resources
  - http://medicaldevices.bsigroup.com/en-GB/technologies/ivd/

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