Scope & Definitions

Interventional Studies
- Making available, putting into service

Obligations of Economic Operators

Person Responsible for Regulatory Compliance

UDI and Registration

Summary of Safety and Performance

Classification & Conformity Assessment

Notified Bodies

Common Specifications

Reference Laboratories

Scrubtinity of Class D devices

Clinical Evidence & Performance Evaluation

Post-market performance follow-up

Interventional Studies
- Performance study applications;
  Sponsor & Database

Post-market surveillance

Vigilance
Overview

**Key impacts for IVDs under the IVDR**

1. Time line for IVDR
2. Scope
3. Classification
4. Conformity Assessment
5. Clinical Evidence
6. Scrutiny
7. Post-market
8. Companion Diagnostics
9. In-house Manufacture
10. Other Aspects of Significance
   - What now…
1. Time line
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)
IVDR update

Medical devices: deal reached on new EU rules

25/05/2016 | 20:15 | Press release | 283/16 | Health

On 25 May 2016, the EU agreed new rules on medical devices and in vitro diagnostic medical devices.

The Netherlands presidency of the Council and representatives of the European Parliament reached a political agreement. It is still subject to the approval by the Council’s Permanent Representatives Committee and of the Parliament’s ENVI committee.

- Political agreement has been reached between Council and Parliament
- Consolidated *draft* text issued dated 15-Jun; clean version 27-Jun-2016
- Translation of text and legal linguist review

Publication in the *Official Journal of the EU*
Alignment of the MDR and IVDR

• ‘...There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices,

• whereas the horizontal aspects common to both sectors should be aligned.’
Transitional arrangements for IVDR

**Entry into Force**
- Q1 2017

**EI F + 6m**
- Q3 2017

**Publication end 2016/ Q1 2017**
- Publication + 6 months
  - NBs apply for designation

**5 Year Transition**
- Mfrs can meet IVDD or IVDR

**Date of Application**
- Q1 2022
- Q1 2024

**Date of Application**
- No IVDD CE may be issued

**Implementing Acts**
- Class A IVDs (non-sterile) under the IVDR can be placed on market under IVDR
- CE Certificates can be renewed by a NB during the transition
  - Max expiry DoA + 2 years

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2. Scope
Scope – Definitions that apply

Medical Device

- ‘medical device’ means 'medical device' as defined in Regulation (EU) No [Reference to the future Regulation on medical devices].
**Scope – Definitions that apply**

**Medical Device**

- ‘medical device’ means ‘medical device’ as defined in Regulation (EU) No [Reference to the future Regulation on medical devices].

**In Vitro Diagnostic MD**

- …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…to be used *in vitro* for the examination of specimens, including blood and tissue donations…from the human body,
- solely or principally for…providing information..
Scope – Definitions that apply

**Medical Device**

- ‘medical device’ means ‗medical device‘ as defined in Regulation (EU) No [Reference to the future Regulation on medical devices].

**In Vitro Diagnostic MD**

- concerning a physiological or pathological *process or state*;
- concerning congenital *physical or mental impairments*;
- 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.
What is NOT an IVD…

- (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 devices or those 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.
Consideration of scope…

**Placing on the market**
- *'placing on the market'* means the first **making available** of a device, other than a device for performance study, **on the Union market**;

- *'making available on the market'* means any **supply** of a device, other than a device for performance study, **for distribution, consumption or use** on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
Consideration of scope...

Placing on the market

- 'placing on the market' means the first making available of a device, other than a device for performance study, on the Union market;

- 'making available on the market' means any supply of a device, other than a device for performance study, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation.
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.
3. Classification
New Classification of IVDs by risk

- Risk classes A, B, C & D (where D is the highest) – Annex VII
- Implementing acts and Guidance
- Borderline issues will be referred to the CA of the Manufacturer or Authorised Rep; if this is different to the CA of the NB, they will consult
- Role of Medical Device Coordination Group (MDCG)
- If there is more than one potential application for a test, and the intended use is of the lower classification, there must be a specific exclusion in the labelling
- Where more than one rule applies, the highest classification will be used.
Classification

Rule 1
Blood screening
High risk disease

Rule 2
Blood or tissue compatibility

Rule 3
Infectious disease
Cancer testing
Companion diagnostics
Genetic testing
Congenital screening

Rule 4
Self testing
High risk near-patient tests

Rule 5
Specific IVD reagents
Instruments
Specimen receptacles

Rule 6
None of the other rules

Rule 7
Controls no assigned values

Class B self-tests
- Pregnancy tests
- Fertility tests
- Cholesterol tests
- Detection of glucose, erythrocytes, leucocytes and bacteria in urine
New classes of IVD devices

Class D

High public health risk, high personal risk

Examples
- HIV 1/2,
- Hepatitis C virus
- Hepatitis B virus
- HTLV I/II
- Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems
- CHAGAS
- Syphilis (used to screen blood donations)
New classes of IVD devices

**Class D**

High public health risk, high personal risk

Examples
- HIV 1/2,
- Hepatitis C virus
- Hepatitis B virus
- HTLV I/II
- Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems
- CHAGAS
- Syphilis (used to screen blood donations)

**Class C**

High personal risk, moderate to low public health risk

- Syphilis (diagnosis only)
- Neonatal screening for metabolic disorders e.g. PKU
- Rubella
- Cancer markers
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests
# New classes of IVD devices

## Class D

**High public health risk, high personal risk**

- HIV 1/2
- Hepatitis C virus
- Hepatitis B virus
- HTLV I/II
- Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems
- CHAGAS
- Syphilis (used to screen blood donations)

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**High personal risk, moderate to low public health risk**

- Syphilis (diagnosis only)
- Neonatal screening for metabolic disorders e.g. PKU
- Rubella
- Cancer markers
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests

## Class B

**Moderate to low personal risk, low public health risk**

- Thyroid function
- Infertility assays
- Clinical chemistry
- Self-test devices listed as not Class C
- ‘Near patient tests’ are classified in their own right
## New classes of IVD devices

<table>
<thead>
<tr>
<th>Class D</th>
<th>Class C</th>
<th>Class B</th>
<th>Class A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High public health risk, high personal risk</strong></td>
<td><strong>High personal risk, moderate to low public health risk</strong></td>
<td><strong>Moderate to low personal risk, low public health risk</strong></td>
<td><strong>Low personal risk, low public health risk</strong></td>
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<td>Hepatitis B virus</td>
<td>Infertility assays</td>
<td>Wash buffers</td>
</tr>
<tr>
<td>HTLV I/II</td>
<td>Blood grouping ABO, Rhesus, Kell, Kidd and Duffy systems</td>
<td>Clinical chemistry</td>
<td>Specimen receptacles</td>
</tr>
<tr>
<td>CHAGAS</td>
<td>Syphilis (used to screen blood donations)</td>
<td>Self-test devices listed as not Class C</td>
<td>Instruments</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Culture media</td>
</tr>
</tbody>
</table>

### Class D Examples
- HIV 1/2
- Hepatitis C virus
- Hepatitis B virus
- HTLV I/II
- Blood grouping ABO, Rhesus, Kell, Kidd and Duffy systems
- CHAGAS
- Syphilis (used to screen blood donations)

### Class C Examples
- Syphilis (diagnosis only)
- Neonatal screening for metabolic disorders e.g. PKU
- Rubella
- Cancer markers
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests

### Class B Examples
- Thyroid function
- Infertility assays
- Clinical chemistry
- Self-test devices listed as not Class C
- ‘Near patient tests’ are classified in their own right

### Class A Examples
- Accessories
- Wash buffers
- Specimen receptacles
- Instruments
- Culture media
4. Conformity Assessment
Conformity Assessment

A
EU Declaration of Conformity
Annex III

B
Quality Management System Assurance
Annex VIII

C
Quality Management System Assurance
Annex VIII

D
Type Examination Annex IX (includes Technical Documentation)

Assessment of Technical Documentation on representative basis - under Article 40, 4.

Assessment of Technical Documentation on representative basis - Annex VIII 3.3 (c)

Production Quality Assurance Annex X

Production Quality Assurance Annex X

For Companion Diagnostics CA consultation

For Companion Diagnostics CA consultation

Assessment of Technical Documentation

Batch Verification

Batch Verification
Conformity Assessment

A
- EU Declaration of Conformity Annex III

B
- Quality Management System Assurance Annex VIII

C
- Quality Management System Assurance Annex VIII
- Type Examination Annex IX (includes Technical Documentation)

D
- Quality Management System Assurance Annex VIII
- Type Examination Annex IX (includes Technical Documentation)

Annex VIII 3.3 (c): Assessment of Technical Documentation on representative basis - Annex VIII 3.3 (c)?

For Companion Diagnostics CA consultation

For Companion Diagnostics CA consultation

Batch Verification

Batch Verification

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Certificates issued under Annex VIII

**Class B & C devices**

- EU Quality Management System certificate (Annex VIII, sec 3 & 4)
  - Accompanied by assessment of technical documentation on representative basis for each generic device group
    (Likely needed for Class B devices, *to be confirmed*)
Certificates issued under Annex VIII

**Class B & C devices**
- **EU Quality Management System certificate** (Annex VIII, sec 3 & 4)
  - Accompanied by assessment of technical documentation on representative basis for each generic device (Likely needed for Class B devices, to be confirmed)

**Class D & Others specified**
- **EU Quality Management System certificate** (Annex VIII, sec 3 & 4)
- **EU Technical Documentation Assessment certificate** (Annex VIII, sec 5)
  - For each Class D device to be placed on the market
  - Reference laboratory will verify claimed performance and Common Specification requirements – *needs to be positive outcome*
  - MDCG consultation if no Common Specification
  - Verification of manufactured batches (Class D)

*Self-test and near patient tests, Classed B-D; Companion Diagnostics*
Certificates issued under Annex VIII

**Class B & C devices**
- EU Quality Management certificate (Annex VIII, sec 3 & 4)
  - Accompanied by assessment of technical documentation on a representative basis for each generic device (likely needed for Class B devices, to be confirmed)

**Class D & Others specified***
- EU Quality Management System certificate (Annex VIII, sec 3 & 4)
- EU Technical Documentation Assessment certificate (Annex VIII, sec 5)
  - For each Class D device to be placed on the market
  - Reference laboratory will verify claimed performance and Common Specification requirements – *needs to be positive outcome*
  - MDCG consultation if no Common Specification
  - Verification of manufactured batches (Class D)
- OR EU Technical Documentation Assessment certificate (Annex VIII, sec 6)
  - For each device* to be placed on the market
  - Drug consultation for Companion Diagnostics

*Self-test and near patient tests, Classed B-D; Companion Diagnostics*
5. Clinical Evidence
‘Clinical benefit’ consideration

Clinical benefit of an IVD = Accurate medical information ≠ Final clinical outcome
Clinical Evidence

- New requirement for Clinical Evidence

- **Clinical evidence** = 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 and safety, when used as intended by the manufacturer

- Based on harmonised guidance

- **GHTF documents** (IMDRF archive):
  - 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
Clinical Evidence

- New requirement for Clinical Evidence
- **Clinical evidence** = 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 and safety, when used as intended by the manufacturer

- Based on harmonised guidance
- **GHTF documents** (IMDRF archive):
  - 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
Scientific validity
Refers to the association of an analyte to a clinical condition or physiological state

Analytical performance
Refers to the ability of an IVD medical device to correctly detect and measure a particular analyte

Clinical performance
Ability to yield results that relate to a particular clinical condition or physiological state for the intended use and in accordance with target population, and where applicable to the intended user

For established analytes, this may be from literature; but for companion diagnostics or novel analytes this needs to be established

Performance requirements similar to IVD Directive essential requirements

Data to support diagnostic accuracy compared to reference test; information related to expected values
Performance Evaluation

- Sum total = Clinical Evidence

- **Process** of Performance Evaluation

- Done according to a Performance Evaluation Plan

- Collated as a Performance Evaluation Report

- Continuous during life-time of the device
Scientific Validity

Refers to the association of an analyte to a clinical condition or physiological state

For established analytes, this may be from literature; but for novel analytes or companion diagnostics this would need to be established
Scientific Validity

Refers to the association of an analyte to a clinical condition or physiological state

For established analytes, this may be from literature; but for novel analytes or companion diagnostics this would need to be established

Analytical Performance

Refers to the ability of an IVD medical device to correctly detect and measure a particular analyte

Performance requirements similar to IVD Directive essential requirements
Scientific Validity

Refers to the association of an analyte to a clinical condition or physiological state

For established analytes, this may be from literature; but for novel analytes or companion diagnostics this would need to be established

Clinical Performance

Ability to yield results that relate to a particular clinical condition or physiological state for the intended use and in accordance with target population, and where applicable to the intended user

Data to support diagnostic accuracy compared to reference test; information related to expected values

Analytical Performance

Refers to the ability of an IVD medical device to correctly detect and measure a particular analyte
Performance requirements similar to IVD Directive essential requirements
Expectations for Performance

**Performance Evaluation Plan**, as well as a file of **Clinical Evidence** will form part of the Technical Documentation, as a **Performance Evaluation Report**

- **Clinical Performance studies** may be required, unless justified

**Interventional performance studies** – new requirements

- In line with clinical trial expectations for clinical trials of medicinal products

**Clinical Evidence** will need to be updated

- Consolidated text states if there has been a ‘trigger’, then the PE Report will need updating

**Post-market Surveillance** and **Post-market Performance Follow-up (PMPF)**
6. Scrutiny
Additional scrutiny of High Risk devices
Class D

Pre-certification

- Common Specifications
- MDCG review of Novel devices
- Reference Laboratories

Post-certification

- Summary of Safety & Performance
- EUDAMED
- NB to notify CA
- Periodic Safety Update Reports
- Reference Laboratories
Class D

Pre-certification

Common Specifications

MDCG review of Novel devices

Reference Laboratories

Post-certification

Summary of Safety & Performance

EUDAMED

NB to notify CA

Periodic Safety Update Reports

Reference Laboratories
7. Post-market
Post-market obligations

- **Vigilance** requirements
  - Incident Reporting
  - Trending

- **Post-market Surveillance Plan & Post-market Surveillance**
  - Reviewed as part of Surveillance visits
  - Post-market surveillance Report (Class A & B); or
  - Periodic Safety Update Reports (Class C & D)

- **Post-market Performance Follow-up (PMPF)**

- For **Class C & D devices**, updates to the *Summary of Safety and Performance*, at least annually
  - Will be publicly available
Certificates issued under Annex VIII - surveillance

Class C

- EU Quality Management System certificate (Annex VIII, sec 3 & 4)
- Substantial changes
  - Potential audit or assessment
  - Supplement to EU QMS certificate
- Annual surveillance audits
  - Inc Post-market Surveillance Plan
- Unannounced on-site audits, at least every 5 years
- Sampling of technical documentation
Certificates issued under Annex VIII - surveillance

Class C

- EU Quality Management System certificate (Annex VIII, sec 3 & 4)
- Substantial changes
  - Potential audit or assessment
  - Supplement to EU QMS certificate
- Annual surveillance audits
  - Inc Post-market Surveillance Plan
- Unannounced on-site audits, at least every 5 years
- Sampling of technical documentation

Class D & Others specified*

- EU Quality Management System certificate (Annex VIII, sec 3 & 4)
- Surveillance as per C (without sampling)
- EU Technical Documentation Assessment certificate (Annex VIII, sec 5 or 6)
- Significant device changes
  - Potential conformity assessment or supplement to EU Tech Doc Assessment certificate
  - Possible Ref Lab consultation if changes impact compliance with the Common Specification (Class D)
- On-going verification of manufactured batches (Class D)

*Self-test and near patient tests, Classed B-D; Companion Diagnostics
8. Companion diagnostics
Definition

**Companion Diagnostic**
means a device which is essential for the safe and effective use of a corresponding medicinal product to:
- identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
- identify, before and/or during treatment, patients likely to be at increased risk for serious adverse reactions as a result of treatment with the corresponding medicinal product;
IVDR, Annex VIII 6.2

**Examination of the design of companion diagnostics**

a) Manufacturer applies to Notified Body for examination of technical documentation

b) Documentation to enable assessment of conformity with the IVDD

c) Notified body consults with the European Medicines Agency (EMA) or country competent authority (CA)

d) EMA or CA gives opinion to the Notified Body within 60 days

e) Notified body gives due consideration to EMA/CA input

f) Manufacturer to notify the Notified Body of changes. Notified Body determines if a new assessment is needed. Notified Body seeks EMA/CA input
NB / Drug Competent Authority consultation

**Notified Body (NB)** reviews the requirements to the Essential Principles including risk management. **NB** also audits the QMS.

**NB** assessors to have expertise in Companion Diagnostics and appropriate technologies e.g. IHC, FISH, ELISA, NAT.

**Dx Manufacturer** submits Companion Diagnostic IVDR Application to the NB.

**Technical File** (design dossier)

**Summary of Safety & Performance** (draft)

**Instructions for Use** (draft)

**NB** contacts the **Competent Authority (CA)** designated (under 2001/83/EC) or EMA (726/2004) as appropriate who will assess the suitability of the device in relation to the medicinal product concerned. **NB** to provide to **CA/EMA**:

- **Summary of Safety & Performance** (draft)
- **Instructions for use** (draft)

**NB** reviews decision from CA / EMA together with Tech File / QMS.

**NB** communicates final review decision to CA / EMA.

**CA/EMA** review and communicate decision to **NB**.

**CA/EMA** Yes 60 days

**CA/EMA** No

**CA/EMA** Request for information from **Dx Mfr** and review.

60 days

**CA/EMA** No

Negative report from CA/EMA to **NB**.

**NB** confirms final review decision to CA / EMA.

**NB** Yes Certificate issued.

**NB** No

No certificate issued.

**NB** reviews decision from CA/EMA.
Open questions with CDx conformity assessments

• Which medicinal product Competent Authority will the Notified Body consult?
• Guidance on expectations of medicinal product CA and NB in the review
• IVDR text is based on parallel co-development of test and drug – ‘real life’ is not necessarily like this
• Will there be a Common Specification?
9. In-house Manufacture

Equivalent to “LDT”
Exemption conditions:

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 systems,
- (b) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation.
- (c) the health institution justifies in its documentation that 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,
Exemption conditions:

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 systems,
- (b) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation,
- (c) the health institution justifies in its documentation that 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.

‘health institution’ means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;

Devices that are manufactured and used within health institutions shall be considered as being put into service.
Exemption conditions:

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 systems**, 
- (b) the laboratory of the health institution is **compliant with standard EN ISO 15189** or where applicable national provisions, including national provisions regarding accreditation. 
- (c) the health institution justifies in its documentation that 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,
Exemption conditions:

- (d) the health institution provides information upon request on the use of such devices to their **competent authority**, which shall include a justification of their manufacturing, modification and use;

- (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,
Exemption conditions:

(f) as regards devices classified as class 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, B and C in accordance with the rules set out in Annex VII;
Exemption conditions:

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

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

- Member States may require that the health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory.
- Member States shall retain the **right to restrict the manufacture** and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

These **provisions do not apply to devices which are manufactured on an industrial scale.**
10. Other aspects of significant impact
Scope & Definitions

Interventional Studies

Making available, putting into service

Obligations of Economic Operators

Person Responsible for Regulatory Compliance

UDI and Registration

Summary of Safety and Performance

Classification & Conformity Assessment

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Reference Laboratories

Scrutiny of Class D devices

Clinical Evidence & Performance Evaluation

Post-market performance follow-up

Interventional Studies

Performance study applications; Sponsor & Database

Post-market surveillance

Vigilance
Other significant impacts

- New General Safety and Performance requirements
- Requirements and increased scrutiny of Notified Bodies
- Increased obligations of Economic Operators
  - Inc. Authorised Representatives, Importers, Distributors
- Person Responsible for Regulatory Compliance
  - Manufacturers (or Auth Rep) with Degree + 1 yr IVD experience; or 4 yrs IVD experience
- UDI and device registration
  - Impact on labelling; phased in under the IVDR
- Requirements for interventional performance studies (or studies with risks to subjects)
- Reference Laboratories
- Vigilance
10. What now...
What now…

Notified Bodies
• Preparing themselves for designation
• NBOG codes will be needed

Manufacturers
• Project Plan according to current texts
• Engage with your/a Notified Body
• Use the Transition Period effectively!
• More in this afternoon’s session.

Other Economic Operators
• Authorised Representatives, Importers and Distributors need to plan to meet new obligations
What now…

Lunch
Exercise

Preparing for the IVDR
Instructions

• Consider how you will use the 5 year transition period
• You will be provided with some plastic cards containing the key topics, milestone dates and some blank cards and pens.
• Put the key activities in date order and consider in which year you would do them to create a high-level a time line

30 minutes
Click here to start
...making excellence a habit™
Useful links

• Current IVDD

• European Commission Recommendation on Unannounced Audits

• Index of MEDDEV Guidance Documents

• European Commission Medical Device Landing Page

• Draft IVDR

• GHTF Archives
  • http://www.imdrf.org/ghtf/ghtf-archived-docs.asp

• BSI IVD Resources
  • http://medicaldevices.bsigroup.com/en-GB/technologies/ivd/

• BSI Webinars
  • www.bsigroup.com/en-GB/medical-devices/resources/webinars/