

EU Medical Device Regulations Update

February 24, 2015





NEW Proposal for Medical Devices Legal Process & Deadlines

Stacy Edelen – Obelis USA Branch Manager

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February, 2015



New Proposals: Background

Why Now?

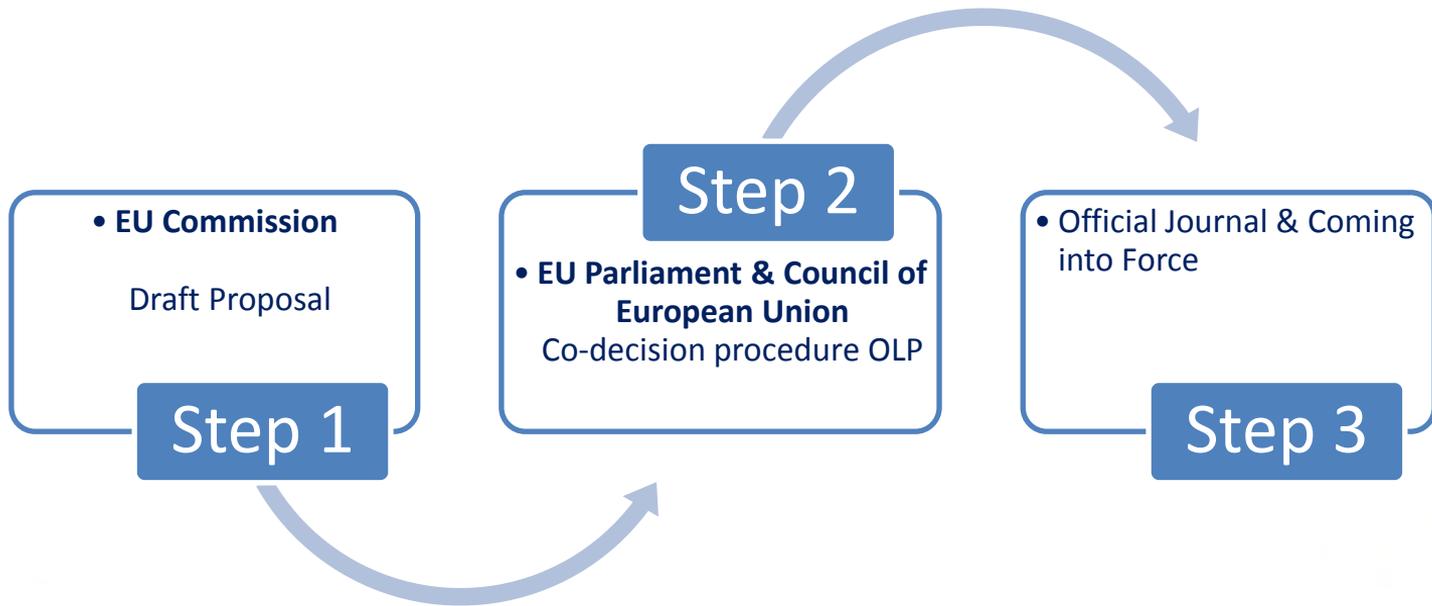
1. The existing EU rules (MDD 93/42/EEC)– dating back to the 1990s – have not kept pace with the technological and scientific progress in the past 20 years.
2. **By the “Directive” system, EU states interpret and implement the current rules in different ways: de-harmonization of the EU market.**
3. Recent years highlighted major difficulties in the traceability & conformity transparency on medical devices in Europe:
 - ✓ Tracing medical devices back to their suppliers found to be a challenge
 - ✓ Patients and Healthcare professionals do not have access to information

New Proposals: Background

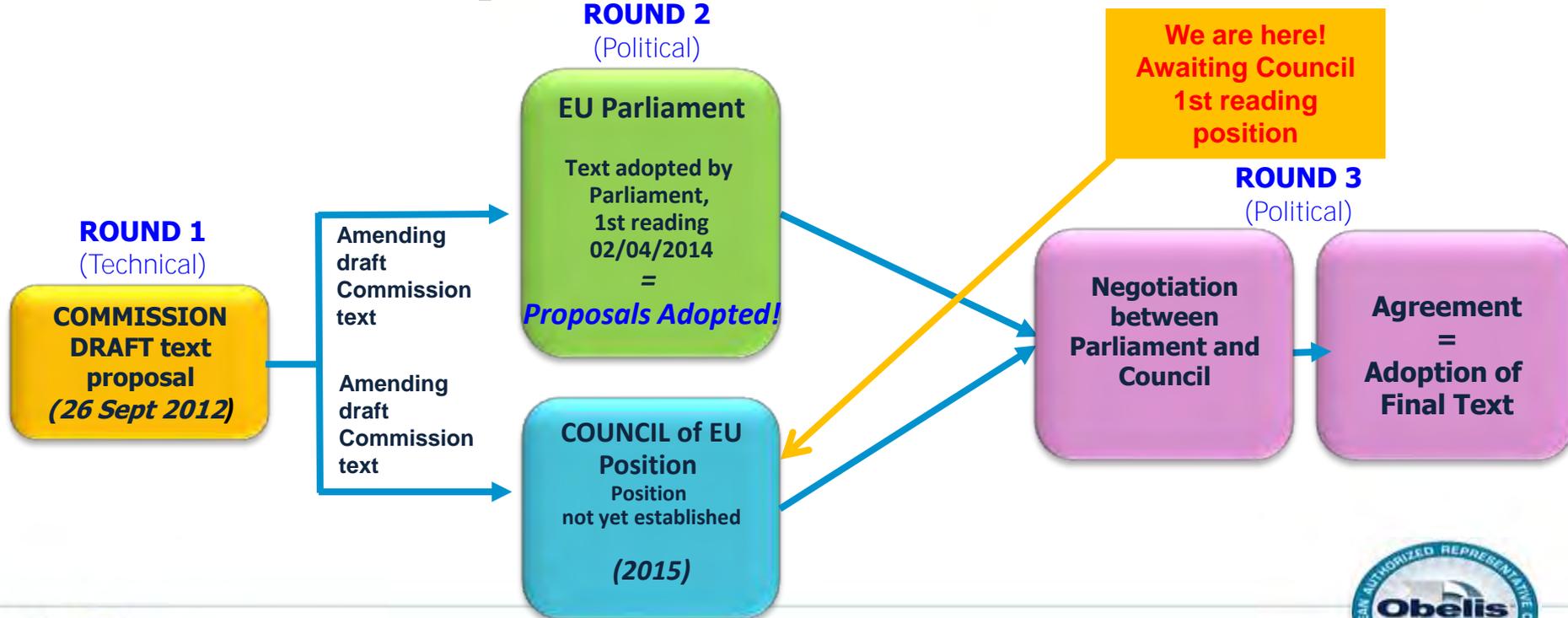
What will change?

- Wider, clearer scope for EU legislation on medical devices
- More Powers to Notified Bodies (e.g. unannounced visits)
- Better traceability in the supply chain and an extended open to the public database (Eudamed)
- Updated classification rules & stricter requirements for clinical data
- Better coordination between national surveillance authorities
- Clearer rights & responsibilities for: manufacturers, importers and distributors, Authorized Representatives, Notified Bodies & Competent Authorities
- The NEW Proposal for medical devices will be a **Regulation**

New Proposals: Legal Process



New Proposals: Present & Future



New Proposals: Deadlines

Implementation deadlines?

- ✓ **2012 (September 26th)** – Proposals adopted by EU Commission
- ✓ **2013-2014** – Ordinary Legislative Procedure
- ✓ **2015** – Target for adoption by Council of the EU & EU Parliament
- ✓ **2015-2016** – Target for initiation of gradual **coming into force**
- ✓ **2016-2019** – Target for the New Regulations to **become applicable** (set to be within 3 years after its entry into force) in the 28 EU states (3 EFTA countries + Switzerland)



New Proposals: Stay Up-to-Date

To follow the legal process of the MD Proposals:

PreLex:

Monitoring of the decision-making process between institutions

Visit: <http://ec.europa.eu/prelex>



SUMMARY

- Currently at **Phase 2-** Council of the EU position to be established
- To **come into force in 2015 & 2016** and be progressively implemented
- **Broadening the Scope & upgrading** the requirements
- **Harmonization** of the 28 EU States + 3 EFTA + Switzerland



New Provisions of the Proposed Medical Device Regulation

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February, 2015



New Provisions

- Assessment of Notified Bodies
- **'Special' Notified Bodies for high risk devices**
- Greatly extended and open to the public database (Eudamed)
- Powerful NEW Committees
- Qualified Person – Manufacturer & Authorized Representative
- Updated classification rules & stricter requirements for clinical data

Assessment of Notified Bodies

- All current NBs will need to be re-certified under the new Regulation
- NBs shall have in-house expertise - no outsourcing of knowledge
- Notified bodies shall make publicly available the list of subcontractors or subsidiaries, the specific tasks for which they are responsible and the declarations of interest of their personnel.
- NBs wishing to be appointed as conformity assessment bodies will be assessed by at least 1 person from the Commission, one person from a different Member State
- For 'special' NB (higher class), EMA is also included.

Notified Bodies for High Class Devices

- The concept of 'Special' Notified Bodies introduced
- Appointed by and supervised by EMA (European Medicines Agency)
- Only 'Special' NBs can evaluate devices:
 - In Class III
 - Those that are implantable
 - Those incorporating a substance,
 - Class IIb intended to administer or remove medicinal products and
 - Those using tissues or cell of human or animal origin. Article 43.a

EUDAMED

- The European Database of Medical Devices will greatly expand to accommodate registrations and information on:
 - Manufacturers, Authorized Representatives, Notified Bodies (with subcontractors) and conformity certificates, importers & distributors
 - Medical devices with UDI information – to ensure traceability
 - Applications for clinical investigations and outcome of clinical trials
 - Summary of safety performance for high risk devices
 - Incident reports, market surveillance and corrective actions, MDCG reports
 - Information will be split towards publically available and restricted access

Powerful New Committees

- Medical Device Coordination Group (MDCG)
 - Providing support for borderline decisions, CTs, clinical investigations, vigilance, appointment of NBs
- Assessment Committee for Medical Devices (ACMD).
 - Provides scientific advice on medical technology, regulatory status of devices and other aspects of implementation of this Regulation

Qualified Person

- Within both the manufacturer's organization and the Authorized Representative, at least one 'qualified person' (for each) to be responsible for regulatory compliance
- Responsibilities include:
 - Conformity of devices prior to release
 - Technical documentation and Declaration of Conformity are up to date
 - Vigilance and market surveillance is carried out as required

Classification Changes

- The Active Implantable and Medical Device Directives will be merged into the proposed Regulation, all Active Implantable Devices, and their accessories, fall under Class III
- Rule 8 modified: Devices in contact with the heart, CCS, CNS are in Class III ***with the exception of sutures & staples***
- Devices containing nanoparticles, intended to be used for aphaeresis, be inhaled or administered rectally or vaginally, that are absorbed or dispersed will all be Class III

SUMMARY

- Upgraded requirements of Notified Bodies require them to be re-certified under the NEW Regulation – **time to assess your Notified Body (!)**
- Special Notified Bodies for Class III devices
- EUDAMED extended with information accessible to the public used (!)
- Broadening Scope to include products not intended for clinical use & the change in classification for certain products
- Qualified Persons for manufacturers and their Authorized Representatives



Electronic Labeling Requirements

EU 207/2012

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February, 2015





Current Requirements for the Label

- Name or trade name & address of the manufacturer
- Name & address of AR
- Details to identify the contents
- The word Sterile & the method of sterilisation
- Batch code or Serial number
- Use before date
- Single use
- Custom made/clinical investigation
- Special storage, handling, operating, warnings or precautions
- Year of manufacture for active devices
- Indication of human blood derivative
- A warning where the device contains certain phthalates
- Detachable components to be identified by batch No. to detect potential risks

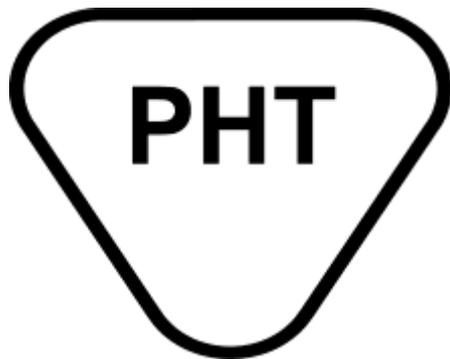
Current Requirements for IFUs

- All information from label except LOT & Expiry date
- Performances & side effects
- Safe combinations of use
- Verifying correct installation & use
- Avoidance of risks connected to implantation
- Reciprocal interferences
- Action if sterile packaging damaged
- Method to reuse including re-sterilisation
- Treatment before use
- Emitted radiation
- Issue date or revision number
- Details allowing medical staff to brief patient
 - Change in performance of device
 - Exposure to environmental conditions
 - Details of medicines intended to be delivered
 - Medicinal substances incorporated
 - Risks of disposal
 - Accuracy of measuring functions

Symbols in EN ISO 980

- | | | | |
|--|--|--|---|
| <ul style="list-style-type: none">• Do not reuse• Use by• Batch or LOT No.• Serial No.• Date of manufacture• Sterile + methods• Aseptic processing | <ul style="list-style-type: none">• Catalogue No.• Caution• Manufacturer• Authorised Representative• Sufficient for ... tests• Performance evaluation | <ul style="list-style-type: none">• IVD device• Temperature limits• Consult IFU• Biological risks• Protect from sunlight• Keep dry• Do not resterilise• Non sterile | <ul style="list-style-type: none">• Control / negative / positive• Contains natural rubber latex• Do not use if packaging is damaged• Sterile fluid path |
|--|--|--|---|

Symbol for “contains phthalates”



Accompanied by
bis (2-ethylhexyl) phthalate (DEHP);
benzyl butyl phthalate (BBP) and
dibutyl phthalate (DBP)
EN 15986:2011



Changes by Proposed Regulation (1)

- Label format should be readable by human and machine (i.e. RFID or bar codes)
- If reusable – processes to clean, disinfect, packaging, number of allowable reuses, validated method of sterilisation, etc
- If not reusable- risk of reuse should be indicated
- IFU to indicate the type of user (lay or professional) & to be lay-friendly

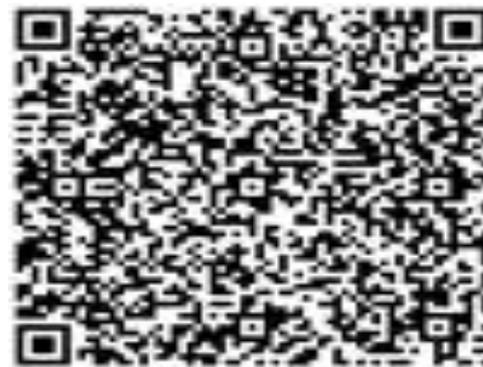


Changes by Proposed Regulation (2)

- The label must state “This product is a medical device”
- Where applicable, that the device is only to be used in a single procedure
- Statement where devices contain nanoparticles, unless bound within the device
- Where applicable, the **Unique Device Identification (UDI)**

Are these familiar?

- Symbology similar to these will start appearing on medical devices in the not too distant future



Advantages of UDI

- Facilitates recalls – identification of stock & location
- Adverse event reporting and postmarket surveillance – record of stock used & unused, allows target safety alerts
- Identification & Traceability – though distribution to patient use Accurate transfer of device details to patient records
- Improve procurement – inventory management & accounting
- Reduction in counterfeiting – correct device identification

EU 207/2012 – Electronic Labeling

- Active implantable medical devices, as covered by the AIMDD 90/385/EEC Directive
- Implantable medical devices and fixed installed medical devices, under the Medical Device Directive (MDD 93/42/EEC)
- Medical devices and their accessories fitted with built-in system visually displaying the instructions for use, under both AIMDD 90/385/EEC and MDD 93/42/EEC
- Stand-alone software covered by MDD 93/42/EEC

SUMMARY

- EN 980:2008 (EU standard for symbols) is the applicable standard
- UDI system will be implemented progressively starting with high class medical devices
- Products containing **phthalates** classified at CMR substances should be indicated clearly on the label alongside the symbol
- **E-labeling** of certain medical devices in force as of **March 1st, 2013**
- Commission to generate acceptance criteria for **single use devices**



Thank you for your attention!

Questions?



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Unannounced visits by Notified Bodies Impact on The Manufacturer and his suppliers

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February, 2015





EU Commission Recommendation

25.9.2013

EN

Official Journal of the European Union

L 253/27

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 24 September 2013

on the audits and assessments performed by notified bodies in the field of medical devices

(Text with EEA relevance)

(2013/473/EU)



Objective

Provides general requirements and guidelines for

- Design dossier examination (Annex I)
- Quality system assessment (Annex II)
- **Unannounced audits (Annex III)**

to verify compliance with MDD, AIMD, IVDD



For whom?

- Notified Bodies
- Member States:
 - ✓ Supervise the practice of notified bodies
 - ✓ Evaluate the notified bodies' readiness } deciding on/ withdrawal of designation
- Manufacturers
- Subcontractors / Suppliers



General requirement

The notified bodies should:

- ***in addition*** to the initial, surveillance or renewal audits, visit the **manufacturer**, its critical **subcontractor** (process) or critical **supplier** (crucial component/entire device)
- **without prior notice** ("unannounced audits")
- in accordance with the principles set out in **Annex III** to verify the day-to-day compliance with legal obligations.



Annex III – Unannounced audits

- Timing is unpredictable
- At least 1x / 3 years
- Increased frequency if:
 - devices bear a high risk
 - devices are frequently non-compliant
 - reasons to suspect non-conformities of the devices or of their manufacturer
- Takes not less than 1 day
- At least 2 auditors



Annex III – Unannounced audits

- Visit:
 - Manufacturer
 - One of the premises of the manufacturer's critical subcontractors or supplier
 - if the main part of the design development, manufacturing, testing or another crucial process is located with the subcontractor or supplier.



Annex III – Unannounced audits

- Check **recently produced** sample for its conformity with
 - technical documentation
 - legal requirements.
- Verification of the **traceability** of **ALL** critical components and materials
- Verification of manufacturer's traceability system
- The check should encompass:
 - **file review**
 - and, if necessary in order to establish the conformity, **testing** of the device.



Annex III – Unannounced audits

- Prior to carrying out product testing
 - The Notified Body defines the sampling and test procedures in advance
 - The Notified Body needs all the relevant **technical documentation** including **previous test protocols** and **results**.
 - The test may also be performed by the manufacturer, its critical subcontractor or crucial supplier **under observation** of the Notified Body



Annex III – Unannounced audits

- Statistical requirements defined for sample selection:
 - At least 3 device types if < 99 device types.
 - Per each additional 100 device types, 1 more device type to be sampled and tested
- Samples can be taken from recent manufactured product at the end of the production chain or from the manufacturer's warehouse.
- Notified Bodies may take samples from the market, if necessary with support by the competent authorities,



Definition of Device Type

- A device is considered a different type for testing purposes where technical differences could affect device safety or performance, such as:
 1. Intent of use
 2. Mode of operations
 3. Components or materials (only if they effect the above 2)



Annex III – Unannounced audits

- Verification whether the manufacturing activity ongoing at the time of the unannounced audit is in line with the QMS requirements and manufacturer's documentation
- At least two (2) critical processes:
 - one which has a high likelihood of non-conformity
 - one which is particularly safety relevant

Examples:

Design control, establishment of material specifications, purchasing, control of incoming material or components, assembling, sterilization, batch-release, packaging, or product quality control.

Impact on contracts!

Contract between NB and manufacturer includes:

- Continuously inform the NB on the periods when devices will not be manufactured.
- Authorize the NB to end the contract as soon as their unannounced access to the premises (manufacturer, subcontractors, supplier) is no longer assured. => **No sales!**
- Measures to be taken by notified bodies to ensure the security of their auditors
- Financial compensation for the unannounced audits including, the device acquisition, its testing and security arrangements.



Impact on contracts!

Contract Manufacturer – Subcontractor/Supplier:

- Relevant (subcontracted) QMS elements shall be implemented
- Guarantees access, facilitation and security NB auditors
- Costs
- If a **visa** is needed to visit the country where the manufacturer/subcontractor/supplier is located, the contractual arrangements should contain, as an annex, an invitation to visit the manufacturer at any time and an invitation which leaves the date of signature and the date of visit open (to be filled-in by the NB body).



SUMMARY

- Unannounced Audits: **STARTED in 2014 !!!**
- The Manufacturer to make sure he is aware and ready = implemented in QMS
- Update the contracts with subcontractors/suppliers covering:
 - QMS
 - Access of NB – unannounced.
 - Costs coverage
 - Impact on contract when access is denied.



NEW Proposal for Medical Devices Impact on European Authorized Representative

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February, 2015





Background

Directive 93/42/EEC (including Amendment 2007/47/EC) provides the following requirements:

1. One single **EAR** mandatory for any device sold in the EU
2. **EAR** must keep available technical documentations available to Competent Authorities
3. **EAR** must fulfill certain delegated tasks by the manufacturer

Background

Role of the **EAR** remains undefined by Medical Devices Directives

Questions:

- **What are the responsibilities of the EAR?**
- **What tasks are to be delegated to the EAR?**
- **What technical documentations the EAR to keep available?**





Legal references

	DIRECTIVE	MEDDEV	REGULATION
	MDD 93/42/EEC	MEDDEV 2.5/10	COM(2012) 542
Publication date ?	June 14th 1993	January 2012	September 2012
When ?	June 14th 1998	Immediately applicable	Under Ordinary Legislative Procedure
What ?	Essential requirements to MD, subject to national transposition	Official EU Commission guidance document explaining legislative acts (Directives & Regulations)	Essential requirements to MD, no national transposition

EAR as a Requirement

- For all non EU manufacturers
- For all Class I, Is, Im, custom made, IIa, IIb, III, AIMD, IVDs (including self-testing and annex II list A/B)
- For all devices for clinical investigation (MDD-AIMD) and performance evaluation (IVD)

DIRECTIVE	MEDDEV	REGULATION PROPOSAL
1. To designate a single EAR (per device model)	1. To designate a single EAR (per device model)	1. To designate a single EAR (per device model) <u>REMINDER:</u> ➤ Even for devices bearing CE marking without circulating in the EU ➤ Even with a registered place of business in the EU but with no relevant activities



EAR Qualifications

DIRECTIVE	MEDDEV	REGULATION PROPOSAL
<p>1. No Mention</p>	<p>1. EAR must possess appropriate knowledge, expertise and resources to assess manufacturer ability to fulfill his obligations.</p>	<p>1. EAR shall have at least one Qualified Person with expert regulatory knowledge. Qualified Person = person responsible for regulatory compliance and has:</p> <ul style="list-style-type: none"> 1) University degree (law, sciences, medicine, pharmacy, engineering) + minimum 2 years experience in regulatory affairs or MD QMS; <p>OR</p> <ul style="list-style-type: none"> 2) 5 years experience in regulatory affairs or MD QMS



EAR Mandate as a Requirement

DIRECTIVE	MEDDEV	REGULATION PROPOSAL
<ol style="list-style-type: none"> To « Designate » a single EAR. No mention of mandate. 	<ol style="list-style-type: none"> To designate a single EAR Contract specifying the tasks delegated to the EAR Minimum mandate as a <u>suggestion</u> <p>REMEMBER : Some national specificities regarding AR (shall be reflected in agreement).</p>	<ol style="list-style-type: none"> To designate a single EAR Written mandate as a <u>requirement</u> Accepted by both parties Provides Minimum mandate requirements EAR requirements in the regulation to be reflected in the mandate



EAR Mandate (Minimum) Content

DIRECTIVE	MEDDEV	REGULATION
1. No Mention	<ol style="list-style-type: none"> 1. EAR should have access to the technical documentation (declaration of conformity, NB certificate, label & IFUs, PMS, Clinical Data, incident reports and information on EU distributors) 2. EAR to assess manufacturer ability to fulfill regulatory obligations. 3. EAR to verify the required information / documentation and necessary processes. 	<ol style="list-style-type: none"> 1. EAR to have <u>permanent immediate</u> access to documentation (declaration of conformity, NB certificate) 2. EAR to provide CA with all the information and documentation 3. EAR to cooperate with CA on any corrective action taken 4. EAR to Immediately inform the manufacturer about complaints and reports 5. EAR to <u>Terminate</u> mandate if manufacturer does not fulfill his obligations under the Regulation. 6. The modalities to change EAR



Documentation Access

DIRECTIVE	MEDDEV	REGULATION PROPOSAL
<p>EAR shall have:</p> <ol style="list-style-type: none"> Access to all documentation necessary for market surveillance 	<p>EAR shall have:</p> <ol style="list-style-type: none"> Access in a timely manner to all documentation necessary for market surveillance 	<p>EAR shall have :</p> <ol style="list-style-type: none"> Permanent immediate access to all documentation necessary for market surveillance In one of the official Union languages.

Changing EAR

DIRECTIVE	MEDDEV	REGULATION PROPOSAL
<p>1. No Mention</p>	<p>1. No Mention</p>	<p>1. Change of EAR - defined by agreement signed by three (3) parties - Manufacturer, outgoing EAR and incoming EAR.</p> <p>2. Agreement to mention (at least):</p> <ol style="list-style-type: none"> 1. The date of termination & date of beginning of mandates with outgoing and incoming EARs. 2. The date of allowed use of outgoing EAR on manufacturer information. 3. Transfer of information 4. Obligation by outgoing EAR to forward complaints or reports to incoming EAR



Devices Notification - Eudamed

DIRECTIVE & MEDDEV

Mandatory by the **EAR**:

1. MDD class I, custom made, KITS
2. AIMDD (custom made devices)
3. IVD (ALL Classes) & Performance evaluation

May be delegated to the **EAR**:

1. MDD & AIMD - Clinical investigation

REGULATION PROPOSAL

Mandatory by the **EAR**:

1. MDD class I, IIa, IIb, III, custom made, KITS
2. AIMDD (custom made devices)
3. IVD (ALL Classes) & Performance evaluation
4. MDD & AIMD - Clinical investigation
5. MDD, IVD & AIMD- Incident/Vigilance reports

- Electronic EU registration by **U**nique **D**evice **I**dentifyer
- Integrated system (all inclusive) publicly available



Conformity Assessment

DIRECTIVE & MEDDEV

1. Tasks may be delegated to the AR:
E.g.,: Establish the declaration of conformity,
conformity assessment application

REMEMBER:

- **NB shall Verify that manufacturers based outside EU have appointed an EAR**
- **NB shall Audit EAR contract, which must demonstrate appropriate delegation of responsibilities.**

REGULATION PROPOSAL

1. Tasks may be delegated to the AR:
E.g.,: Establish the declaration of conformity,
conformity assessment application

REMEMBER:

- **NB shall Verify that manufacturers based outside EU have appointed an EAR**
- **NB shall Audit EAR contract, which must demonstrate appropriate delegation of responsibilities.**
- **EAR on label, CE certificate, Declaration of conformity.**



Manufacturer non-compliance

Directive	MEDDEV	REGULATION PROPOSAL
<ol style="list-style-type: none"> No mention of EAR role 	<ol style="list-style-type: none"> EAR shall inform manufacturer if he considers non-conformities EAR should bring issue to CA in case of disagreement EAR shall Terminate his contract with the manufacturer if non compliance engages EAR responsibility EAR should notify CA & NB of such termination 	<ol style="list-style-type: none"> Terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation. Inform NB and CA <p>=> Implicitly EAR should verify compliance !</p>



SUMMARY

1. A single **EAR** for any **CE Marked device** mandatory (sold in/out EU)
2. Single **EAR** to have one "**qualified person**"
3. Single **EAR** designated by **legal mandate** accepted by both parties
4. Legal mandate must mention **minimum requirements**
5. Permanent and immediate access to **Technical Documentations**
6. Additional agreement to replace **EAR** (outgoing/incoming EAR)
7. Device Notifications to **Eudamed** – by **EAR**, with **UDI** and **public**
8. **EAR** to **terminate** mandate and **report**, in case of non-conformities



Review of **EAR** agreement

- ❖ As per all mentioned above, the **EAR** is a **critical supplier** in reference to the manufacturer conformity with EU regulations.
- ❖ Review the agreement (mandate) with your current **European authorized Representative, today**, and ensure it is in conformity with the MEDDEV and the Medical Device Regulation.



RoHS # 2 (Recast) Directive 2011/65/EU

Impact on Medical Devices

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February, 2015





Introduction

What happened?

- 1) The new RoHS Directive 2011/65/EU (RoHS 2) entered into force on July 21st 2011 with implementation period of 18 months.
- 2) RoHS 2011/65/EC transposed into national laws by 2nd January 2013
- 3) RoHS 2011/65/EU repealed RoHS 2002/95/EC on 2nd January 2013
- 4) RoHS 2011/65/EU fully applicable to medical devices on July 22nd 2014



Introduction

Key Differences between RoHS 1 and RoHS 2?

1. A gradual extension of the requirements to **all electrical and electronic equipment** (EEE), cables and spare parts.
2. A system to continuously include **new hazardous substances** in EEE
3. Clearer rules for granting, renewing or deleting **exemptions**
4. Consistency with other **EU-Legislation**: CE Marking, Declaration of Conformity, Authorized Representative & REACH Regulation



Introduction

Purpose?

- 1) Prevent risks to human health and the environment
- 2) E.E.E. may not exceed maximum concentration values (by weight) of:
 1. ***Lead – 0.1%***
 2. ***Mercury – 0.1%***
 3. ***Cadmium – 0.01%***
 4. ***Hexavalent chromium – 0.1%***
 5. ***Polybrominated biphenyls (PBB) – 0.1%***
 6. ***Polybrominated diphenyl ethers (PBDE) – 0.1%***



Introduction

- ❖ Periodic reviews of the list of restricted substances will take place after the coming into force (July 22, 2014).
- ❖ Substances in REACH Regulation (EC 1907/2006) Annexes XIV and XVII will be taken into account.



Scope

1. RoHS 2001/65/EU Article 3.1 – what is **EEE**?

- ❖ ***‘electrical and electronic equipment’ or ‘EEE’** means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;*



Scope

“This Directive shall, subject to paragraph 2, apply to EEE falling within the categories set out in Annex I.”

1. Large household appliances.
2. Small household appliances.
3. IT and telecommunications equipment.
4. Consumer equipment.
5. Lighting equipment.
6. Electrical and electronic tools.
7. Toys, leisure and sports equipment.
8. **Medical devices** (including IVDs)
9. Monitoring and control instruments including industrial monitoring and control instruments.
10. Automatic dispensers.
11. Other EEE not covered by any of the categories above.



Scope

Annex IV – “Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments”

1. Annex IV provides **20 product types** (medical devices & others) with exemptions from Article 4 (1) of the RoHS Directive (mostly X-Ray devices)
2. Most exemptions refer only to **Lead**, some to **Mercury** & few to **Cadmium**
3. Restrictions on **Hexavalent chromium**, **Polybrominated biphenyls (PBB)**, **Polybrominated diphenyl ethers (PBDE)** fully applicable in medical devices



Scope

1. From 3 January 2013 **cables** are in scope of RoHS (!) - unless they specifically belong to an EEE or a combination of EEE that is outside the scope of RoHS.



Scope

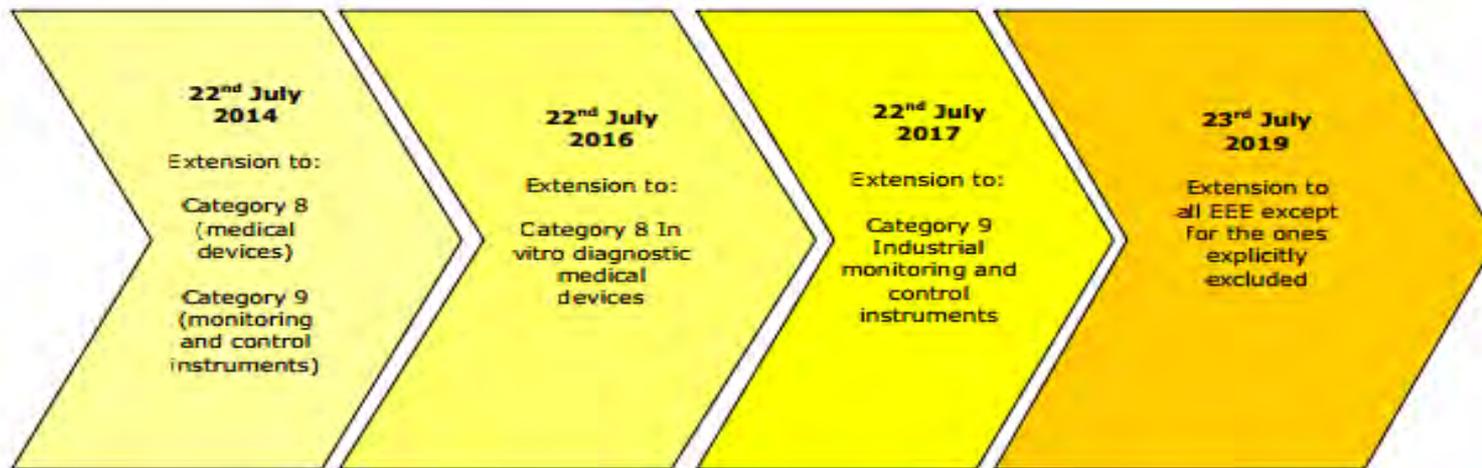
Is my product falling under RoHS - Classification?

1. *Is my product EEE? (Article 3.1)*
 2. *Is it excluded from the scope? (Article 4.2)*
- ❖ *If you answer **'Yes'** to question 1 and **'No'** to question 2 – your product must **fulfill the requirements of RoHS** (!)*



Implementation Deadlines

- Substance restrictions will gradually extend to all product categories.





Directive Requirements

Manufacturers obligations:

1. Substance restrictions ensured in **Design & manufacture** - [Article 4](#)
2. Draw up **technical documentations** available in EU for **10 years** - [Article 7\(b\), 9 \(g\)](#)
3. On his sole responsibility, **Declare Conformity** - [Article 7\(b\), 7\(c\)](#)
4. Mark product (or packaging) with company name, trademarks, trade name and **EU address** at to be contacted for inspection - [Articles 7\(h\), 9\(d\)](#)
5. Affix the **CE Marking** & Ensure products remain in conformity - [Article 7 \(a\), 7\(c\), 7\(e\)](#)
6. Record **non-conformities/recalls** & take actions to conformity – [Article 7\(i\), 9\(f\), 10\(c\)](#)
7. Distributors, Authorized Representative & Authorities **informed** - [Articles 7\(f\), 9\(e\)](#)
8. Fully cooperate with **National Authorities** – [Article 9\(h\)](#)



Directive Requirements

Authorized Representative obligations:

1. Assume the role only under a **written mandate** - [Article 8 \(a\)](#)
2. Keep the **EU declaration of conformity** and the **technical documentation** at the disposal of national surveillance authorities for **10 years** - [Article 8 \(b\)](#)
3. Provide **EU authorities** with all the **information and documentation** - [Article 8 \(b\)](#)
4. Cooperate with **EU authorities**, at their request, on any action taken to **ensure compliance** - [Article 8 \(b\)](#)



Directive Requirements

Importers, Distributors obligations:

1. Cooperate with **EU authorities**, at their request, on any action taken to **ensure compliance** - [Articles 7\(j\), 9\(h\)](#)
2. Distribute only EEE **in conformity** with the Directive(s) - [Articles 9\(a\),\(b\),10\(a\)](#)
3. Stop distribution & take action if **suspects non-conformities** – [Article 9\(c\)](#)
4. Communicate with **Authorized Representative** and EU authorities - [Articles 7\(i\), 9\(f\), 10\(c\)](#)
5. Keep a register of **non-conforming EEE** and recalls - [Articles 9\(e\)](#)



Demonstrate Compliance

Testing

- RoHS testing would normally include tests such as:
 - ✓ ICP-MS, ICP-OES
 - ✓ GC-MS, GC-ECD
 - ✓ FTIR
 - ✓ UV-vis
- **X-Ray Fluorescence** test can be used as a pre-screening test as it focuses primarily on the parts of a product with the highest risk of containing RoHS substances. If XRF screening finds no RoHS substances, there is almost no need to conduct additional tests.



Demonstrate Compliance

Technical Documentation

- RoHS Technical Documentations (**evidence of conformity**) should include:
 1. A General Description of the product
 2. Conceptual design and manufacturing drawings with explanations
 3. A list of the harmonized standards, applied in full or in part with explanations
 4. Results of design calculations, examinations and test reports
 5. Declaration of Conformity

Demonstrate Compliance

Technical Documentation

- Guidelines to RoHS Technical Documentations :
 1. Annex II of **Decision No 768/2008/EC** – Module A
 2. European Harmonized Standard, EN/ISO **50581:2012**
 - This European Standard specifies the technical documentation that the manufacturer needs to compile in order to declare compliance with the applicable substance restrictions.



Demonstrate Compliance

Testing + Technical Documentations = Conformity

- Materials, components and EEE **tested** for compliance with Article 4 (restricted substance) in accordance with harmonized standards published in the Official Journal of the EU, properly documented in **technical documentation**, shall be presumed to comply with the requirements of this Directive - [Article 16.2](#)



SUMMARY

1. Deadline for conformity of **Medical Devices** with RohS: *July 22nd 2014*
2. Deadline for conformity of **IVDs** with RohS: *July 22nd 2016*
3. Conformity attained through **testing** and **technical documentation**
4. Manufacturers to **declare conformity** under their own responsibility
5. Manufacturers to issue a **Declaration of Conformity**
6. Manufacturers to designate **Authorized Representative** (if Non-EU)
7. **CE marking** as the only conformity marking with RoHS 2011/65/EU .



Thank you for your attention!

Questions?



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INTERNATIONAL
TRADE
ADMINISTRATION

Introducing CSEU's Services for Medical Device Manufacturers

Sylvia Mohr, Standards Specialist

U.S. Mission to the EU

Brussels, Belgium





CSEU – Our Mission and Role

- Part of the U.S. Commercial Service professional staff in 100+ U.S. cities and 75 countries worldwide
- But we're different. No direct trade promotion
- Provide counseling, commercial diplomacy, webinars and specialized research related to:
 - EU technical and legal requirements
 - Market access and compliance issues
- USG Advocacy



Healthcare Teams

- U.S. Export Assistance Centers Healthcare Team led by Ms. Tembi Secrist, Seattle
- One Europe Medical Team led by Ms. Danny Dumon (Brussels, Belgium) and Anette Salama (Duesseldorf, Germany) including 'Affinity Teams'
- Healthcare Technology Resource Guide 2015:

http://www.export.gov/build/groups/public/@eg_main/@byind/@healthtech/documents/webcontent/eg_main_068140.pdf



Commercial Service at USEU

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CSEU 2015 Medical Devices Priorities

- Track legislative process of Medical Device Legislation (undergoing review)
- Monitor proposed ban of use of dangerous substances in medical devices
- Analyze impact on U.S. exporters



Do's and Don'ts

- Be prepared before you go into a market
- Create a checklist: have I addressed safety? Packaging? Metric units?
- Simplify your task – is your supply chain familiar with EU legislation? Can your importer help?
- Verify regularly whether legislation and/or standards are undergoing review
- In in doubt about appropriate classification, don't rely on one source only, check with others
- Don't select a test lab until you have compared several quotes/services
- Look into certification while you're talking to potential importers – don't wait until the deal is done because certification takes time



INTERNATIONAL
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Thank you for your attention!

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(until June 2014)

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