# European Regulations

## 12th AHWP Meeting
## Pre-Meeting Workshop
## Chengdu / PR China

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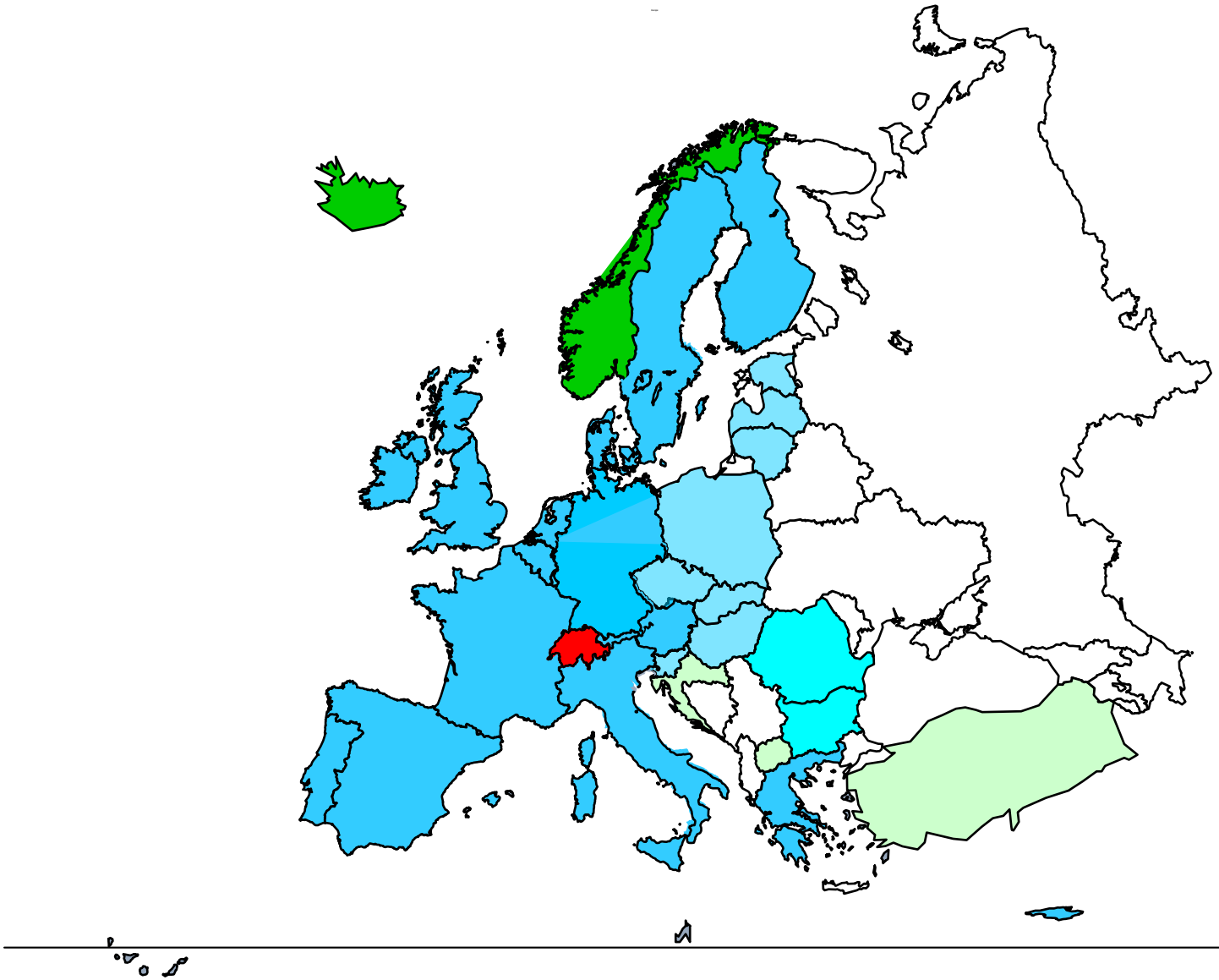
**Synthes Asia Pacific**
**24 October 2007**

SYNTHES®

- Legal situation
- Current Directives
- EU and GHTF
- Outlook to the future

# European Situation

# EU and EFTA/EEA



# Structure of the European system

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## European Commission / DG Enterprise

- Publication of Directives
- Coordination of Notified Bodies for medical devices
- Medical Device Expert Group
- other Working Groups

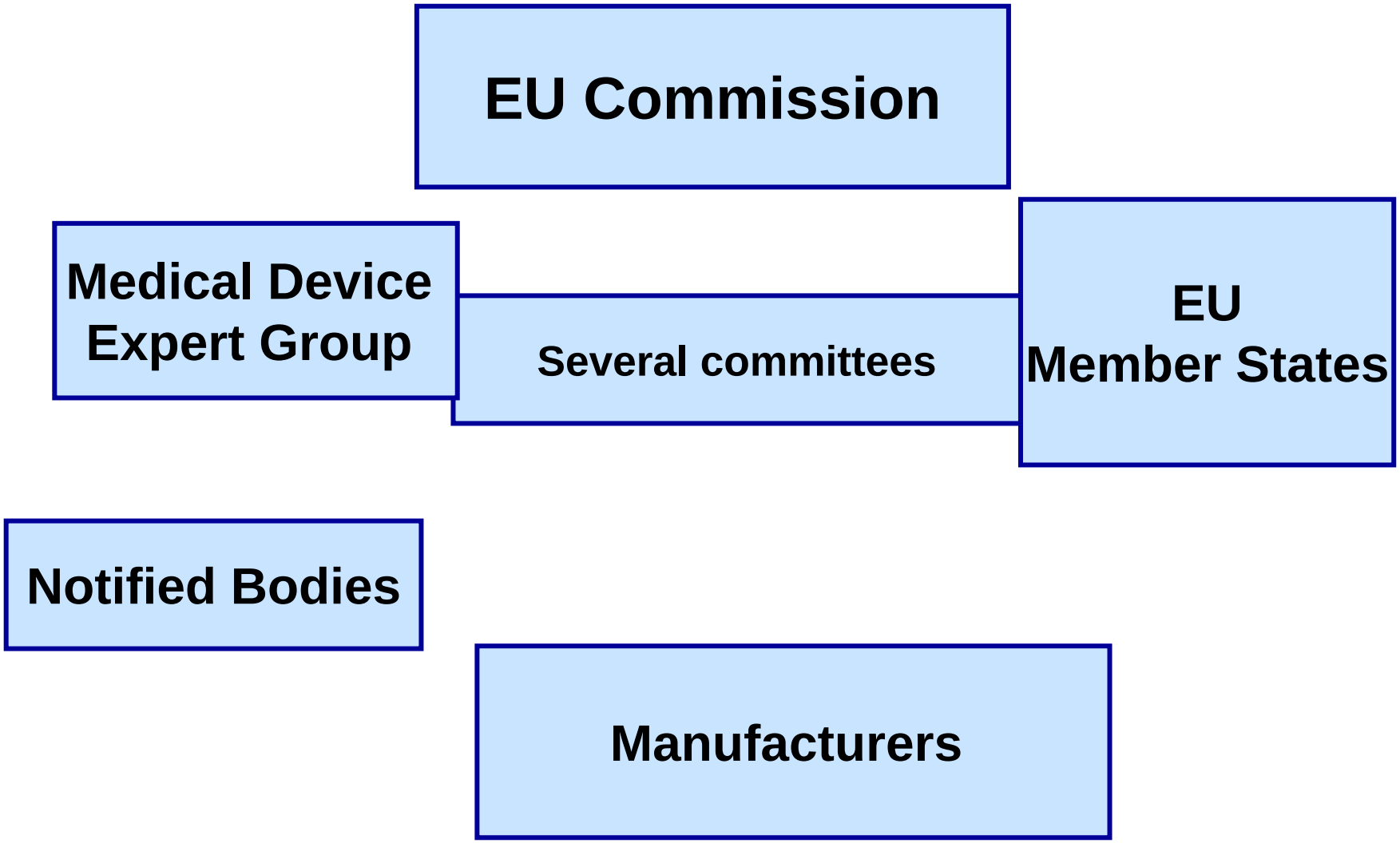
## Member States (including EEA/EFTA countries)

- National Competent Authorities for medical devices
- Exchange of information between national authorities
- Competent Authorities meetings
- bi- / multi-lateral co-operations

# New and global approach

- Based on the **Responsibility of the manufacturer** (quality assurance systems, ongoing risk management)
- A unique set of **Essential requirements** is listed in annex 1 of each directive and must be fulfilled by all devices, no additional national product requirements, European harmonised standards specify the state of the art and confer presumption of conformity
- Unique set of **Evaluation procedures** applicable to all medical devices, notified bodies to be involved for products with risks, CE-marking. **Free movement of goods** within Europe for CE-marked medical devices.
- Collaboration and exchange of information between competent authorities

# Players in Europe



# European Directives

- **Directive 90/385/EEC on active implantable Medical Devices AIMD**

- **Directive 93/42/EEC on Medical Devices MDD**

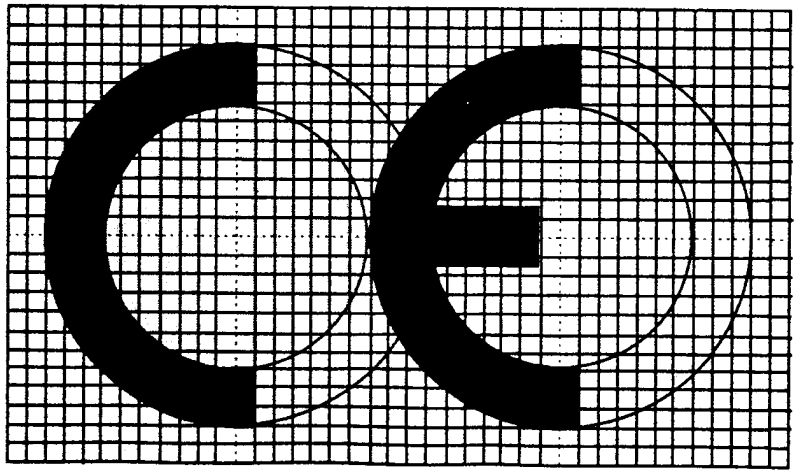
**Reclassification of hip, knee and shoulder joint replacements:**
Directive 2005/50/EC - OJ L 210 , 12/08/2005 (1st Sept. 2009)

- **Directive 98/79/EC on In-vitro Diagnostics IVDD**

**NEW :**

- **Directive 2007/47/EC "on the revision of 90/385/EEC, 93/42/EEC and 98/8/EC"**

# CE mark



Class I devices (w/o measuring function, non-steril),
Professionnel IVD not in annex II of the IVDD

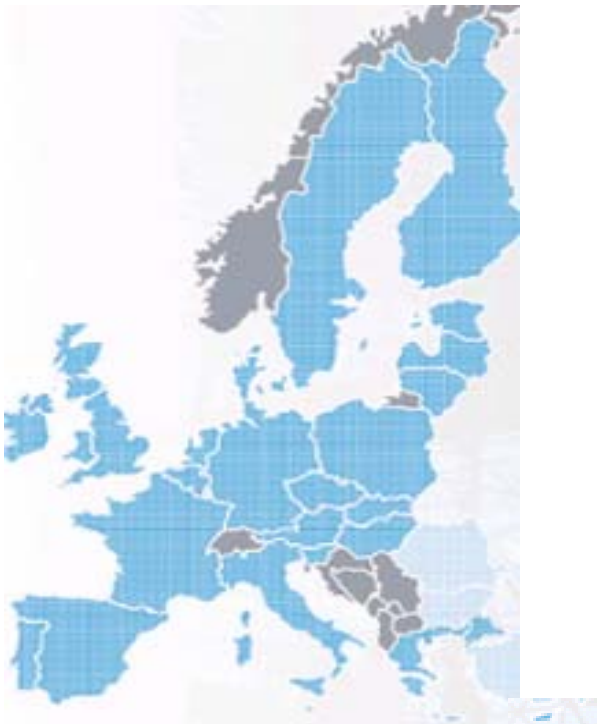
CE

Active implants, devices class $I_s$, $I_m$, IIa, IIb, III,
IVD for lai use, IVD listed in annex II (all with Notified Body number)

CE 0123

# CE mark = quality-passport for the EU

**Free movement of goods for CE-marked medical devices**



**EU Enlargement Jan 2007**
Bulgaria and Roumania

**<u>However</u>:**

- National language requirements to be respected.
- National regulations persist for

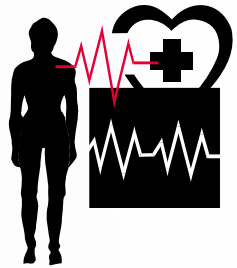
- advertising,
- requirements for delivery to the public
- professional use
- Reimbursement
- taxes applicable to medical devices

# European directives

- “New and global approach directives”
- Must be transposed into national law
- National regulations persist for non harmonized aspects: advertising, delivery to the public, professional use, reimbursement, applicable taxes, details concerning clinical investigations

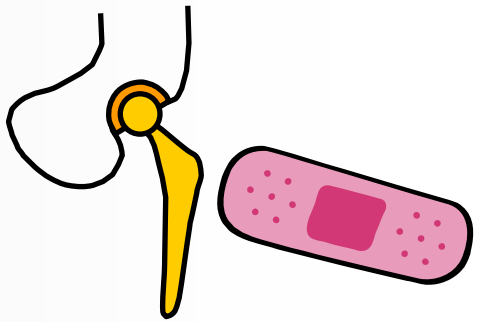
**AIMDD**
Active Implantable Medical Devices Directive

90/385/EEC



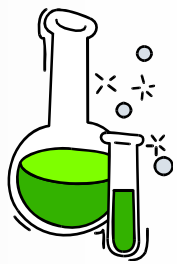
**MDD**
Medical Devices Directive

93/42/EEC



**IVDD**
In Vitro Diagnostic Medical Devices Directive

98/79/CE



# Device classification

- Four, risk based, device classes
- 18 rules for classification based on intended use
- Criteria include duration of contact, invasiveness, anatomical location

- Products are classified by the manufacturer

# Basic elements of the system

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•Consistent essential requirements, technical standards, market access procedures applicable to all medical devices (CE-marking)

• Emphasis given to responsibilities of manufacturers (quality assurance systems, risk management)

• Separation of powers: Competent National Authorities performing control activities independent from organisations performing conformity assessment (market access procedures)

# Elements of Conformity

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**Essential Requirements**

**Conformity Assessment Procedures**
**(Full QM system ISO 13485)**

**Clinical Data**

**Labelling**
**(including languages)**

**Declaration of Conformity**

# Notified Bodies

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- accreditation and notification by State Agencies ( National Authority for accreditation and National Competent Authority for medical devices )

- the Notified Bodies (conformity assessment bodies) have to be independent

  - regular control of the Notified Bodies

  - common approach throughout Europe

# Main activities of the State Authority

- control of clinical trials
- accreditation/notification of the Notified Bodies
- vigilance surveillance and post-market controls
- inspections of manufacturers and wholesalers
- inspections of hospitals (maintenance/repair, sterilisation)
- information to the users: doctors, para-medical staff (nurses), hospital engineers, patients, large public, newspapers

# Authorities and NBs

## Authority

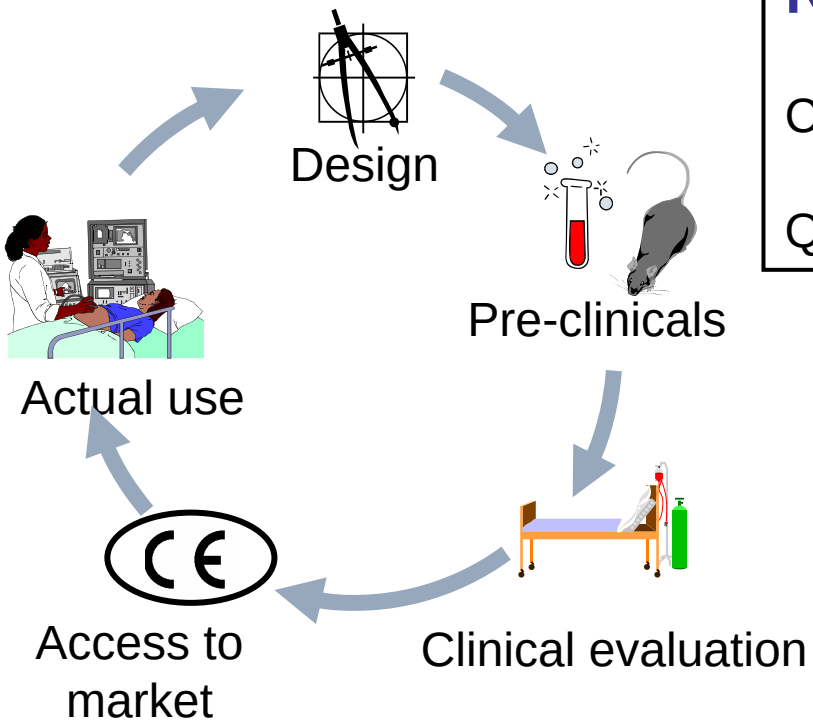
Vigilance/recalls

Market Surveillance

Review notifications class I

Authorization Clinical Studies

Surveillance of NBs

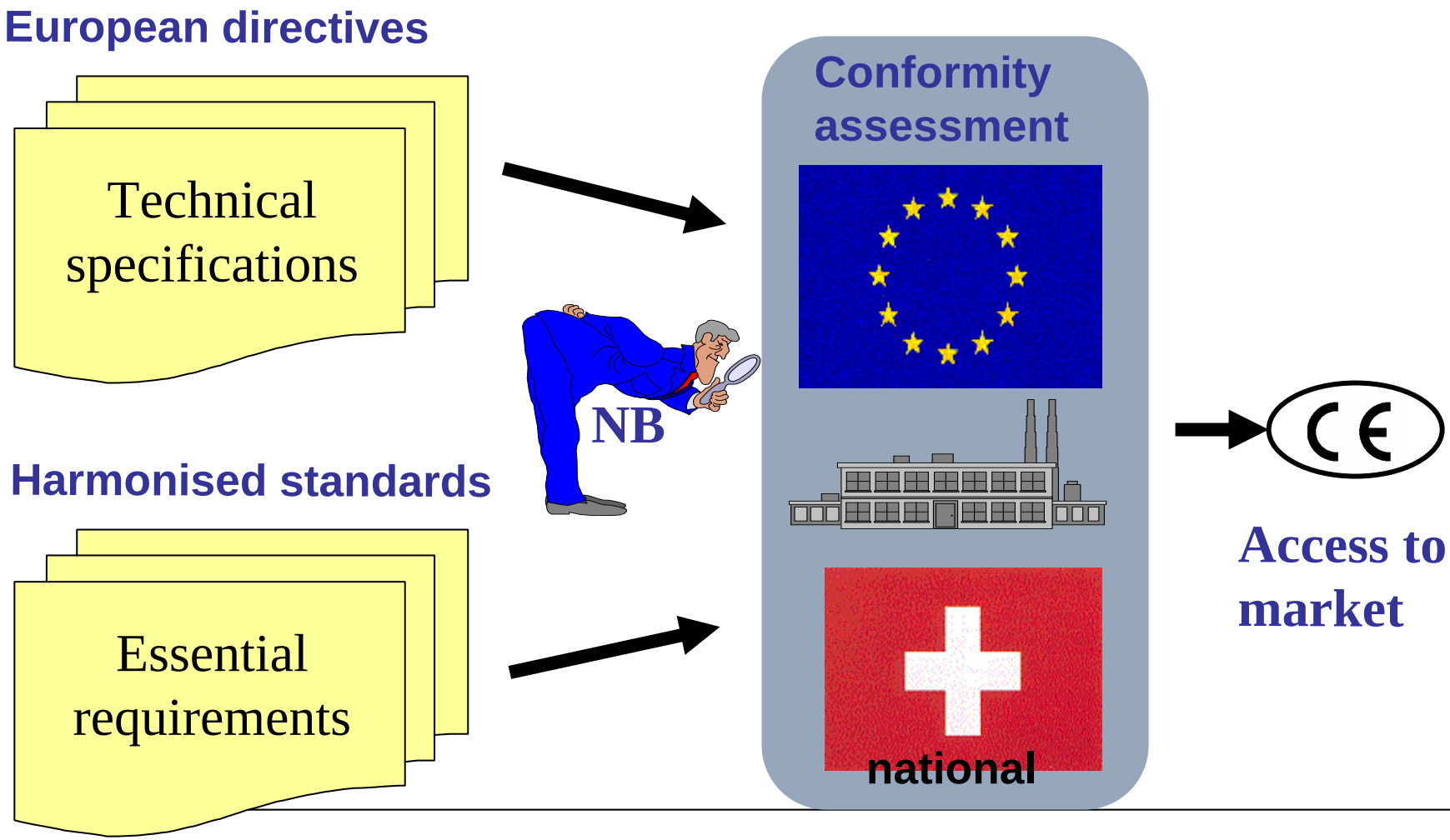



## Notified Body

Conformity assessment

Quality audits

# Regulatory Framework



# Conformity Assessment

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- Class I

- Declaration of c
- Notificati… country wh… d.

**Auto-certification by Mfr**

- Class IIa/ IIb/III

- Product verification
- Production QA
- Product …ng
- Fu… Assurance System w or … design verification.

**Assessed by Notified Body**

# Systematic controls performed by Notified Bodies

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**-1-** No involvement of Notified Bodies

All requirements to be met under the sole responsibility of the manufacturer

- class I non sterile and with no measuring functions, professional IVD not listed in annexe II IVDD
- systems made of CE-marked components
- custom made devices, devices for clinical trials/ performance evaluation

**-2-** Mandatory external evaluation and follow-up: for all other medical devices!

- quality system certification for a given family of devices (ISO 9000 is not enough!)

and/or

- EC type examination / type testing / design dossier review

and/or

- verification by examinations and tests of every product or every batch

**>>> Declaration of conformity (issued by the manufacturer)**
**>>> Certificates (issued by the conformity assessment body)**
**>>> CE-marking (mark applied on the products)**

# State Controls

- Tasks opf the national Competent Authorities (State Authorities)

# European Meetings

- **organised by the EU Commission**
- **organised by member States**
- **organised by the Notified Bodies**
- **organised by the Standard Committees**

# European Meetings and Committees

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European Commission (DG Enterprise) and National Competent Authorities for medical devices:

- direct effects of measures affecting CE-marking of a device
- exchange of vigilance information and measures issuing from market surveillance
- meeting of the **National Competent Authorities** on medical devices
- **Medical Devices Experts Group (MDEG)**
- Notified Bodies Operations Group (NBOG)
- Market Surveillance Operations Group (MSOG)
- Clinical Evaluation Task Force (CETF)
- experts groups (borderline issues, classification issues, GMDN, etc.)
- classification task force

**All meetings with industry representatives, Notified Bodies, experts.**

# Other meetings

**IVD** Technical Working Group

**GMDN** Global Medical Device Nomenclature

**GHTF**

**EUDAMED** European Database for Medical devices

**New and Emerging Technologies**

**Workshop Best Practices** (accession/candidate countries)

**Standards:**

standardization mandates, various technical committees of CEN, CENELEC and ISO dedicated to medical devices standards, recognition procedure for European harmonised standards

# Committees set up under the directives

**Committee on Medical Devices**

- Article 6 section 2 AIMDD
- Article 7 MDD
- Article 7 IVDD

- Composed of the representatives of the Member States
- Chaired by the representative of the Commission

**Committee on Standards and Technical Regulations according to Article 5 of Directive 83/189/EEC**

- Article 6 section 1AIMDD
- Article 6 MDD
- Article 6 IVDD

# Meeting of Competent Authorities (CA)

- **Hosted by the country which is currently holding the Presidency of the EU Council**

  **First half-year 2007 : Germany**
  **Second half-year 2007 : Portugal**
  **First half-year 2008 : Slovenia**

- **Participants: CA‘s from EU, EFTA and applicant countries and the European Commission**

- **No public minutes**

# Notified Bodies
## Conformity Assessment Bodies

# Notified Bodies: Regulatory framework

- Directive 90/385/EEC Active implantable medical devices
  Article 11
  Annex 8: Minimum criteria to be met when designating inspection bodies to be notified
- Directive 93/42/EEC Medical devices
  Article 16
  Annex XI: Criteria to be met for the designation of notified bodies
- Directive 98/79/EC In vitro diagnostic medical devices
  Article 15
  Annex IX: Criteria for the designation of notified bodies

# Responsibility of the Designating Authority

- Designates NBs and defines the scope of designation on the basis of demonstrated competence
- Responsible, through a process of audits/checks for ensuring the NB continously comply with the requirements of the Directives
- Must act on the findings of its audit activities
- Must investigate and act on allegations of poor performance by the NB from whatever source

# Criteria for Notified Bodies

- Independence and impartiality
- Technical, scientific and medical competence
- Ability to carry out all tasks assigned to NB in the desired Annex(es) of the Directive
- Facilities
- Internal quality system
- Ensurance of subcontractor’s competence
- Confidentiality
- Liability insurance

# Important guidance documents

- MEDDEV 2.10: Designation and monitoring of Notified Bodies within the framework of EC Directives on medical devices
  http://europa.eu.int/comm/enterprise/medical_devices/meddev/index.htm
- NBOG: Designating Authorities Handbook
  http://europa.eu.int/comm/enterprise/medical_devices/nb/nbog.htm
- Global Harmonization Task Force (GHTF), SG 4
  Guidelines for regulatory auditing of quality systems of medical device manufacturers (several parts)
  www.ghtf.org

# Accreditation: Standards

EN 45011:1998 General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996)
EA-6/01:1999 EA Guidelines on the application of EN 45011

EN 45012:1998 General requirements for bodies operating assessment and certification/registration of quality systems (ISO/IEC Guide 62:1996)
EA-7/01:2003 EA Guidelines on the application of EN 45012

EA: European co-operation for Accreditation, www.european-accreditation.org

# Designation

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**Application**

**Assessment**

**Designation decision**

**Notification**

# Designation

SYNTHES®

Application

Assessment

Designation decision

Notification

- Applied scope for designation
- General information on organisation and structure
- Quality management
- Personal
- Facilities
- Process descriptions

# Designation

SYNTHES®

Application

Assessment

Designation decision

Notification

- Initial Audit
- Observed Audit
- Curriculum Vitae (CV) of personal
- Subcontractor(s)
- Process description
- Use guidance documents (e.g. checklists)

# Designation

Application

Assessment

Designation decision

Notification

- Agree to designate for the full scope requested
- Agree to designate but for a more restricted scope from that requested
- Agree to designate but with conditions

# Designation

**Application**

**Assessment**

**Designation decision**

**Notification**

- Send the decision to the Notified Body
- Send the decision to the European Commission
- Identification number for CE Marking
- The European Commission publish the Notification in the Official Journal and in the NANDO database

# Surveillance

**Surveillance Audit**

**Observed Audit**

- At least every 18 months
- Scheduling at least 8 weeks in advance
- Duration: 1 – 12 man-day (depends on the amount and complexity of work NB is designated for)
- Use guidance documents (e.g. checklists)

# Vigilance in a Member State

**Goal**: to ensure that the recall is carried out appropriately

- is the planned recall the appropriate measure to reduce the risk associated with the problem?
- are all users informed?
- is the recall implemented in a timely manner?

# Vigilance

# Vigilance exchange in Europe

- Initial/Final reports are available on request to others CAs
- If several similar incidents: a coordinating CA leads the investigation.
- Dissemination of information for incidents where corrective action (including recalls) is to be taken:
  ➔ CA Notification

# EU Database Medical Devices EUDAMED

- Notifications of class I
- Notifications of IVDs
- CE Certificates
- Vigilance
  - Phase I: CA notifications
  - Phase II: all final reports

# The Future

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# Directive 2007/47/EC

**Published in October 2007 and amends 3 directives:**

| | |
|---|---|
| **Active Implantable Medical Devices** | **AIMD 90/385/EEC** |
| **Medical Devices Directive** | **MDD 93/42/EEC** |
| **Biological Products** | **98/8/EC** |

| | |
|---|---|
| **National implementation by EU Member States** | **21 December 2008** |
| **Fully Applicable** | **21 March 2010** |

# Major Changes to 93/42/CE (MDD)

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- Taking into account the **P**ersonal **P**rotective **D**irective 89/686/EEC
- Report on Reprocessing to be submitted in 3 years
- Enforcement of EUDAMED including GMDN translations
- The Notied Body **must** inform other Notied Bodies
- QM system and documents **must** include control of third parties
- Stronger definition which clinical data is expected
- Emphasis on clinical data review by the Notified Body

NOTE

Implementation only in 2010

# European Commission

SYNTHES®

Webpage of the Medical Devices Sector

**http://ec.europa.eu/enterprise/medical_devices/index_en.htm**

**Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.**

**Published: Official Journal of the European Communities**

**OJ L247/ 21 Sept. 2007**

# British Agency MHRA

http://**www.mhra.gov.uk**/home/idcplg?IdcService=SS_GET_PAGE&nodeId=369 SEE: “publications” -> “regulatory guidance”

New Guidance Documents (05 October 2007):

Directives Bulletin No. 2 : The CE Marking

Directives Bulletin No. 3 : The Vigilance System

http://**www.mhra.gov.uk**/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON009818 SEE: “how we regulate” -> “devices”

Medical Devices Directive Revision:

Regulatory Impact Assessment

# Sources of Information

- **EU** (European Commission,DG ENTR, G4 Med. Dev.)
  http://europa.eu.int/comm/enterprise/medical_devices/index.htm
- **GHTF** (Global Harmonization Task Force)
  www.ghtf.org
- **ISO** (International Standard Organization)
  www.iso.org
- **CEN** (European Committee for Standardization)
  www.cenorm.be
- **CENELEC** (Europ. Comm. for Electrotechnical Standard.)
  www.cenelec.org

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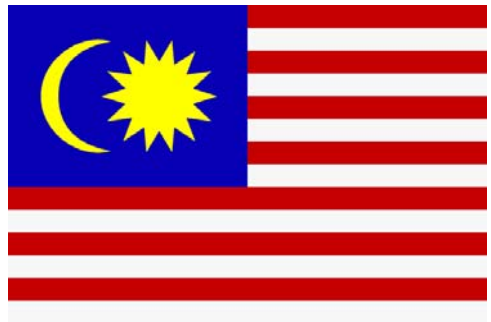

# Thank you!