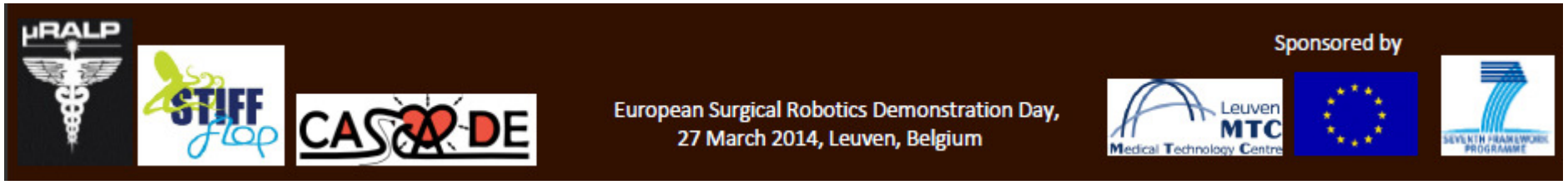
Medical Devices

Notified Bodies and the CE certification Process for Medical Devices

European Surgical Robotics Demonstration Day

27th March 2014, Leuven, Belgium



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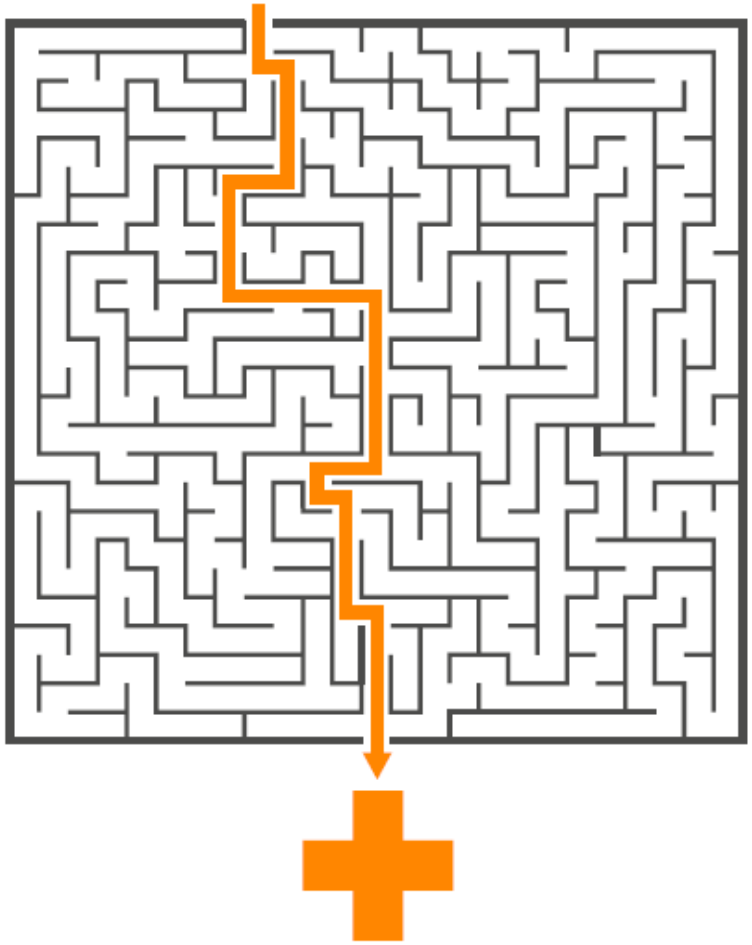


GET YOUR MEDICAL DEVICES TO MARKET
FASTER WHEN YOU KNOW THE WAY

OVERVIEW

The role of Notified Bodies in Medical Device development

1. Prologue: Regulatory framework
2. What is a Notified Body
3. CE marking process and the role of a Notified Body
4. After the CE marking process
5. Future development in the field of medical devices certification in Europe
6. Questions

Disclaimer: the information in this presentation is an interpretation of the regulatory requirements and is not complete

Regulatory framework

PROLOGUE: REGULATORY FRAMEWORK

- Treaty of Rome 1957
  - Created single market (Netherlands, Belgium, German, GH Luxemburg, Italy, France)
  - Defined four freedoms – people, finance, goods, services
  - Removed barriers to trade within EU

PROLOGUE: REGULATORY FRAMEWORK

- New Approach council resolution 1985 - technical harmonisation and standardisation
  - Legislative harmonisation limited to essential requirements that products must meet
  - Technical specifications for products to meet essential requirements are laid down in harmonised standards
  - Application of harmonised & other standards is voluntary, manufacturer may always apply other specifications (with justification)
  - Products compliant with harmonised standards benefit from a "presumption of conformity"

PROLOGUE: REGULATORY FRAMEWORK

- Global Approach council resolution 1989 – certification and testing
  - Consistent approach in regulations by use of modules for conformity assessment procedures & for designation of notified bodies operating those procedures
  - General guidelines and detailed procedures for conformity assessment

PROLOGUE: REGULATORY FRAMEWORK

- **AIMDD**: Directive 90/385/EEC covering active implantable medical devices modified by the directive 2007/47/CE
- **MDD**: Directive 93/42/EEC covering medical devices modified by the directive 2007/47/CE
- **IVDD**: Directive 98/79/EC covering in vitro diagnostic medical devices

- Some amending medical directives (human tissue, breast implants, …)

But also other directive exists:

- **MD:** Directive 2006/42/EC covering machinery
- **PPE:** Directive 89/686/EEC on personal protective equipment
- …

WHAT IS A NOTIFIED BODY

- A **private** organisation, operating in a competitive market
- **Nominated** by a member state

  Nominated based on designated requirements, such as
  - Knowledge, experience,
  - independence
  - Resources to conduct the conformity assessments.
- **Notified** by the European Commission e.g.
  - SGS U.K.: number 0120
  - TÜV Rheinland: number 0197

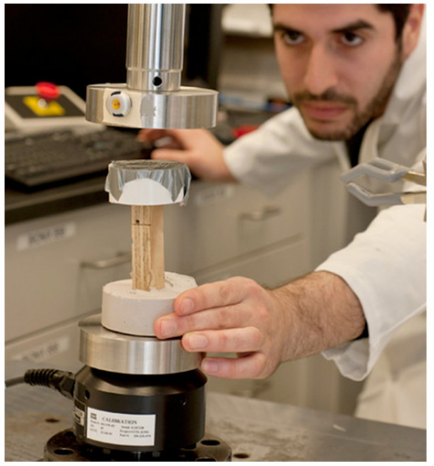
CE 0120

- **Monitored** by a member state: Competent Authori
  - Belgium: FAGG / AFMPS / FAMHP (Federal Agency for Medicines and Health Products)
  - U.K.: MHRA (Medicines and Healthcare products Regulatory Agency)
- **New: Joint Assessments** of medical devices Notified Bodies by Member States and Commission Experts

WHAT IS A NOTIFIED BODY

Role of a Notified Body

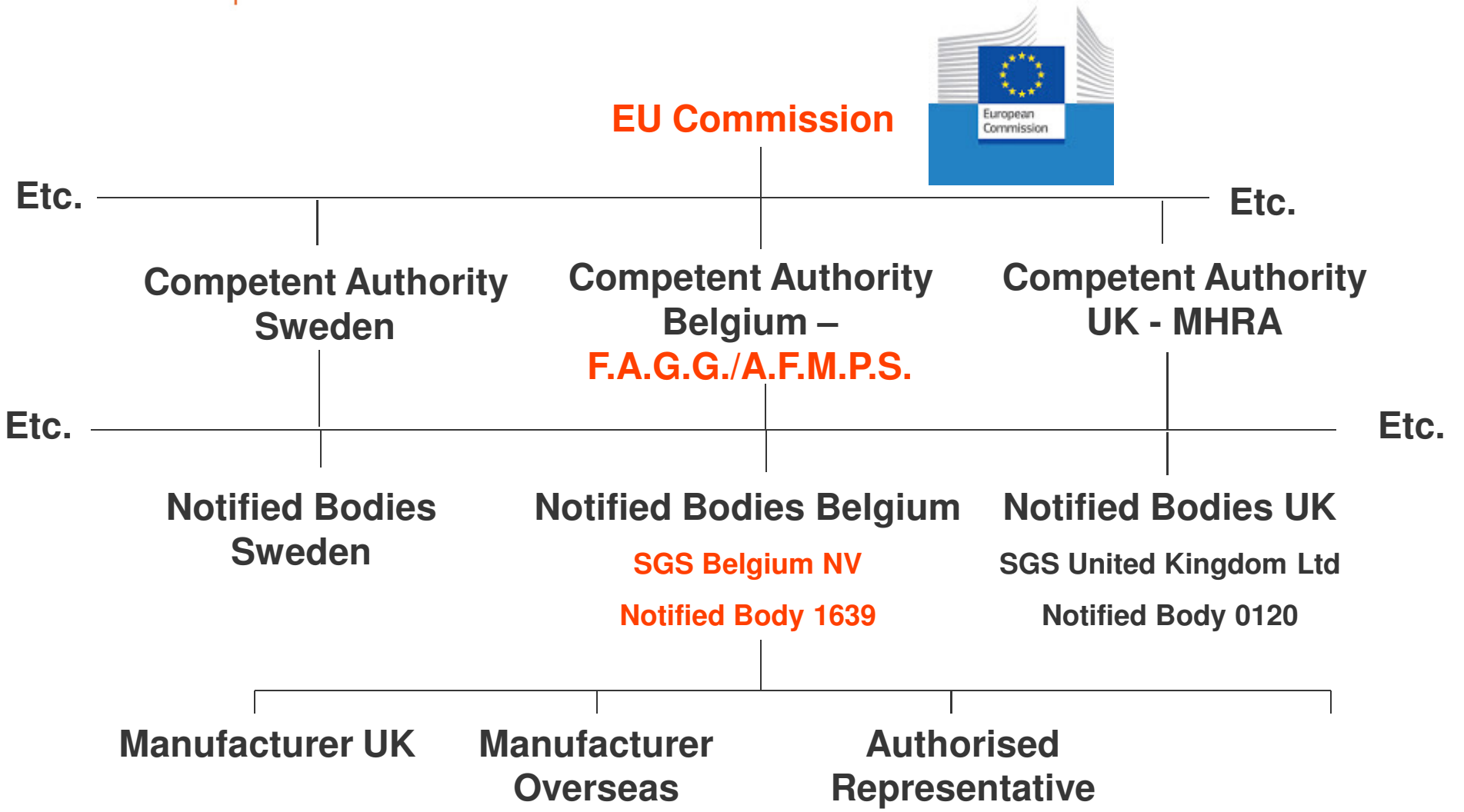
- **Assessing** the manufacturers conformity to the essential requirements listed in the Directive (e.g. MDD, IVDD, AIMDD)
  - Inspection (e.g. one batch)
  - Quality assurance
  - Type examination
  - Design examination
  - Combination of above



- **Issuing** CE certificates (pre-market approval certificate)
- Although we have the knowledge, although we have the competence, ….

=> NO consultancy: it is strictly forbidden by Authorities that Notified Bodies give consultancy to manufacturers (due to conflict of interest)

WHAT IS A NOTIFIED BODY



CE MARKING PROCESS

CE marking: required for many products, e.g. medical device

It states that the medical device

- meets EU essential requirements (safety and performance)
- assessed before being placed on the European Economic Area market (if applicable).

CE marking:

- removing technical barriers to trade

⇨ guarantees the **free movement** of safe and performing products within the E.E.A. (for medical devices: EFTA countries + Turkey)

CE MARKING PROCESS


Directives


Verify requirements

1. Identify the **Directive(s)** that are applicable
2. Choose the **conformity assessment procedure**
3. Identify any **Harmonised European Standards** applicable (not mandatory , presumption of conformity)
4. Is Notified Body required ? Ask a proposal for certification.


Need for notified body?

5. Ensure to comply with all the **essential requirements**
6. Maintain **Technical Documentation**


Check conformity

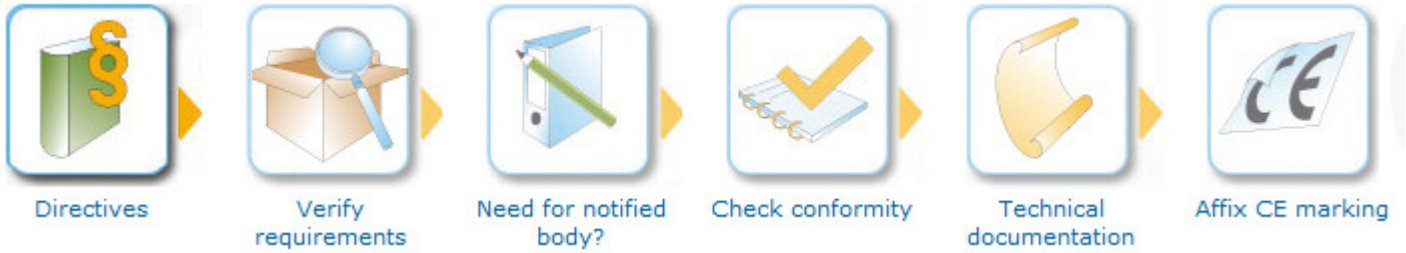

Technical documentation

7. Certification of the QMS and review of the Technical Documentation by the Notified Body (if applicable)
8. **Declaration of Conformity** and the supporting evidence.


Affix CE marking

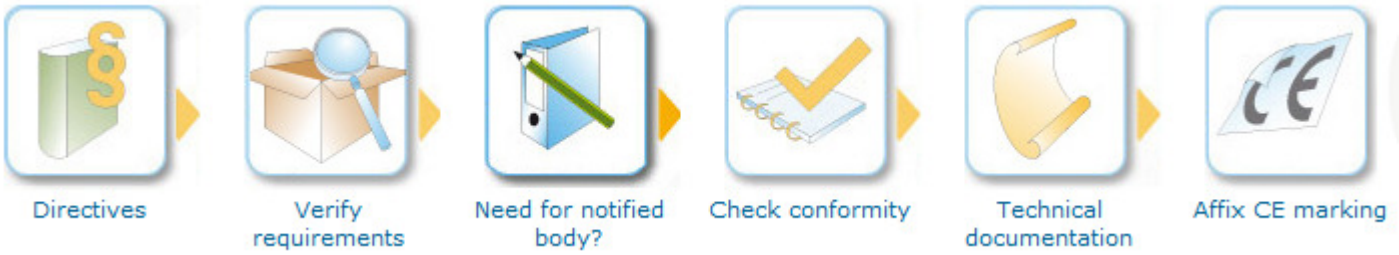
9. Check that no other purely **national** requirements exist
10. Affix **CE marking** on your product

CE MARKING PROCESS: DIRECTIVES



- Is it a medical device according to MDD 93/42/EEC ?
  1. active implantable medical device => AIMD Directive 90/385/EEC
  2. in vitro diagnostic medical device => IVD Directive 98/79/EC
  3. MDD 93/42/EEC
- Is it a machinery?
- Is it a personal protective equipment device?
- …

CE MARKING PROCESS:
NEED FOR NOTIFIED BODY

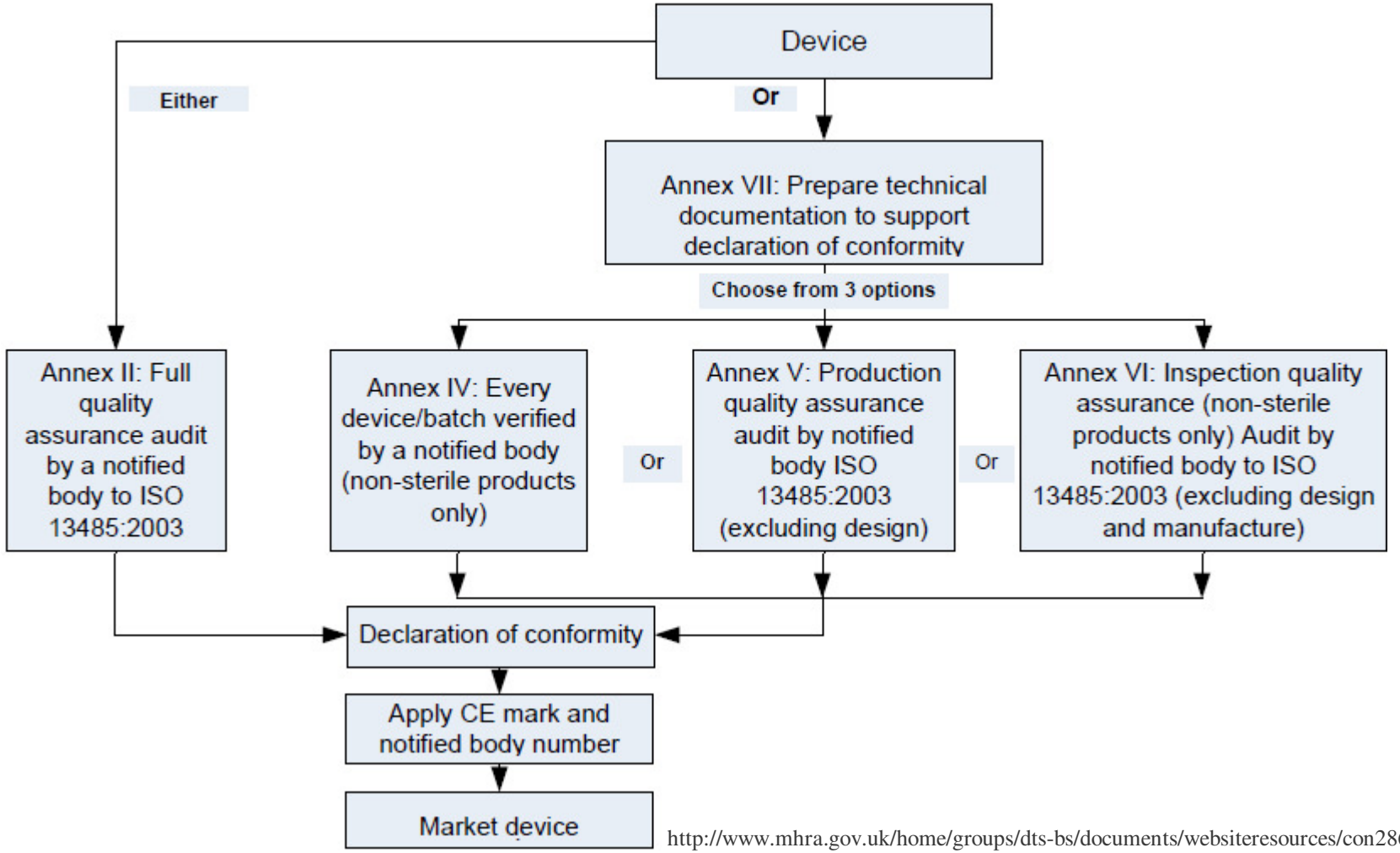


If medical device => check classification (annex IX of MDD)

- class I (low risk) => **no** Notified Body (self certification)
- class I with measuring function => Notified Body
- class I in a sterile condition => Notified Body
- class IIa (medium low risk) => Notified Body
- class IIb (medium high risk) => Notified Body
- class III (high risk) => Notified Body

CE MARKING PROCESS:
CONFORMITY ASSESSMENT ROUTE

Class IIa medical devices – routes to CE marking



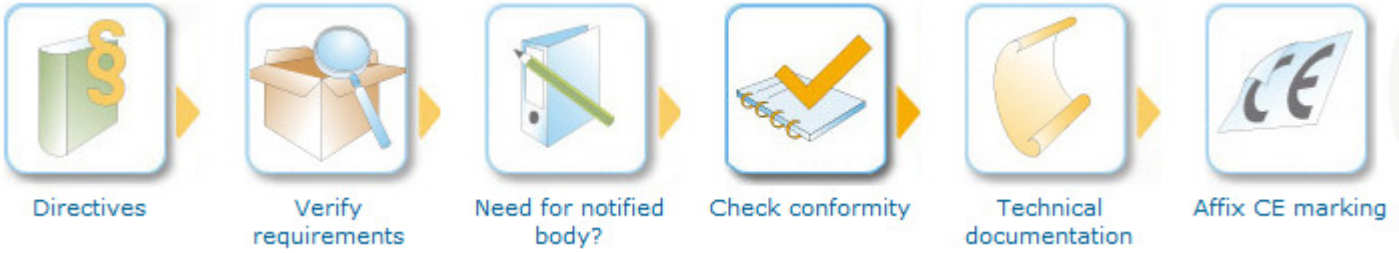
http://www.mhra.gov.uk/home/groups/dts-bs/documents/websiteresources/con286776.pdf

CE MARKING PROCESS: NEED FOR NOTIFIED BODY

- Choose possible conformity assessment procedure: one or combination of Annexes (annexes II to VII of the MDD)

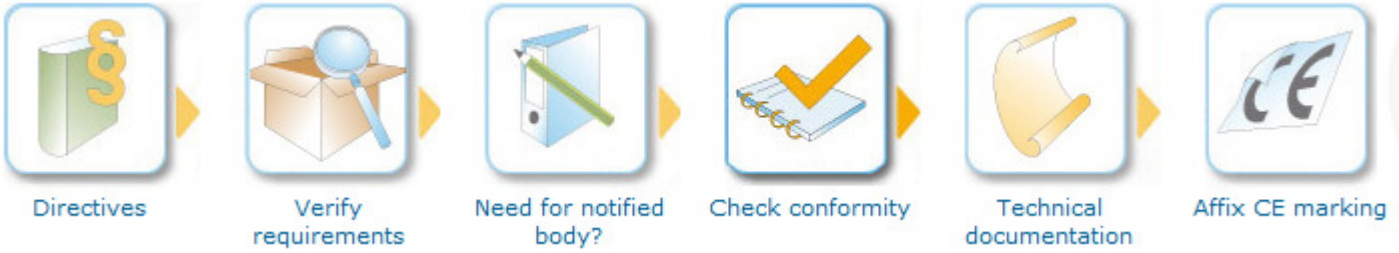
Annex II	Full Quality Assurance – audits of the full QMS
Annex III	EC Type Examination – type testing by the Notified Body
Annex IV	EC Verification, batch or 100% testing by the Notified Body
Annex V	Production Quality Assurance, audits of the QMS without design
Annex VI	Product Quality Assurance, audits of the QMS without design and manufacture

CE MARKING PROCESS:
NEED FOR NOTIFIED BODY



- Choose possible conformity assessment procedure: one or combination of Annexes (annexes II to VII of the MDD)
- Notified Body involvement (if applicable): ask a proposal:
  - Check on selection of correct directive
  - Check on definition ‘medical device’
  - Check on ‘classification’
  - Check on chosen ‘conformity assessment route’
  - Check on critical subcontractors
  - Check on applicable legislation
  - ….

CE MARKING PROCESS:
CHECK CONFORMITY: MEDICAL QUALITY SYSTEM

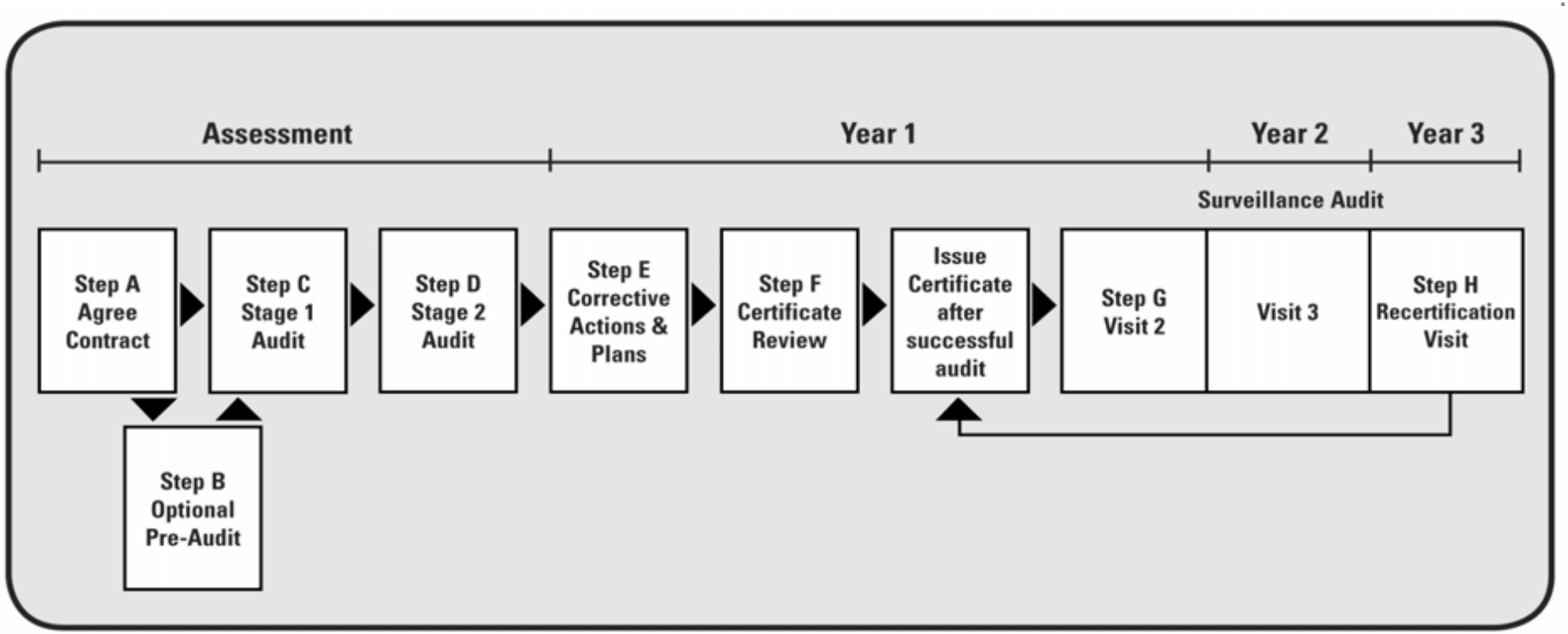


- Medical Quality System !!!

  e.g.
  - Full quality assurance system (annex II)
  - Production quality assurance (annex V)
  - Product quality assurance (annex VI)

- Notified Body involvement (if applicable): audit of medical quality system by Notified Body

CE MARKING PROCESS:
CHECK CONFORMITY: MEDICAL QUALITY SYSTEM

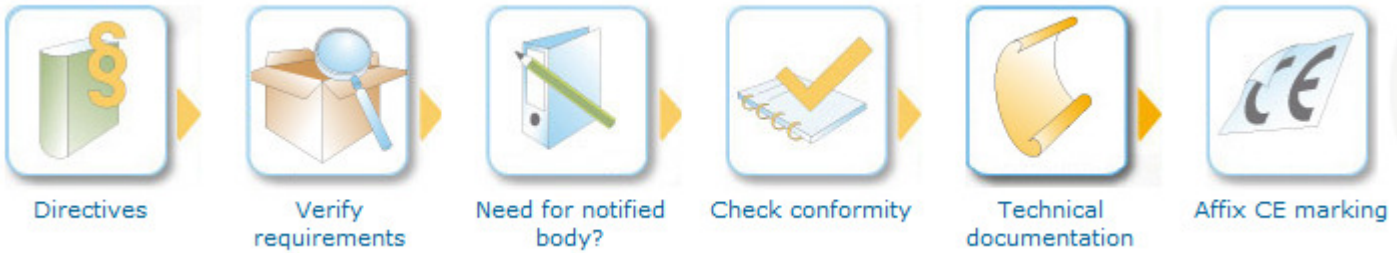


CE MARKING PROCESS:
CHECK CONFORMITY: MEDICAL QUALITY SYSTEM

Quality (management) System: harmonised standard EN ISO13485:2012. But some more requirements in MDD

1. Quality manual / documents / procedures / work instructions
2. Vigilance procedure (incidents or near incidents)
3. How critical subcontractors are controlled
4. Risk management procedure (EN ISO14971:2012)
5. Post market surveillance procedure
6. Post-market clinical follow-up procedure
7. Design ? MDD annex II is most logical conformity assessment route
8. Translation procedure
9. …

CE MARKING PROCESS: TECHNICAL DOCUMENTATION



- Intended for regulators, notified bodies, …not for the company
- described in annex II or VII of MDD :
  - NB-MED document on Technical Documentation
  - S.T.E.D. document from GHTF (IMDRF)
  - class I with measuring function => only measuring function by Notified Body
  - class I in a sterile condition => only sterility aspects by Notified Body
  - class IIa (medium low risk) and class IIb (medium high risk) => technical files reviewed by Notified Body (sampling)
  - class III (high risk) => no sampling: full design dossier by Notified Body

CE MARKING PROCESS: TECHNICAL DOCUMENTATION

Possible structure

1 Device description and product specification

2 'Labelling' (or 'draft labelling')

3 Design and Manufacturing Information

4 Essential Requirements Checklist (including for Machinery directive if applicable)

5 Risk management file

6 Verification and validation of the device, including

- Clinical evaluation (literature; clinical data; clinical trial/investigation)
- Benefit/risk evaluation
- Test reports (EN 60601-1 on electro-mechanical safety; EN 62366 on usability; …)

7 Required declarations

8 Declaration of Conformity

:

AFTER THE CE MARKING PROCESS: LIFE CYCLE

After the manufacturer received the CE certificate…

- Review of the technical documentation and certification audit by your Notified Body => initial certification
- Periodically (at least once a year) surveillance audits by your Notified Body
- Periodically re-review of your technical documentation by your Notified Body at least once every 3/5 years
- Unannounced audit by your Notified Body at least one day (2 auditors) once every 3 years
- Post market surveillance (by the manufacturer), including
  - Post market clinical follow up plan + results
  - State-of-the-art
  - Complaints, incidents,
  - …

AFTER THE CE MARKING PROCESS: LIFE CYCLE

After the manufacturer received the CE certificate…

- Notification to the Notified Body:
  - important changes in QMS
  - changes in product / product gamma
  - Vigilance cases / incidents / recalls / …
  - …
- Extensions in cooperation with the Notified Body
  - new devcies, changed product folio
  - New and/or extended intended use of the device
  - new subcontractor
  - new manufacturing process, new production line, …

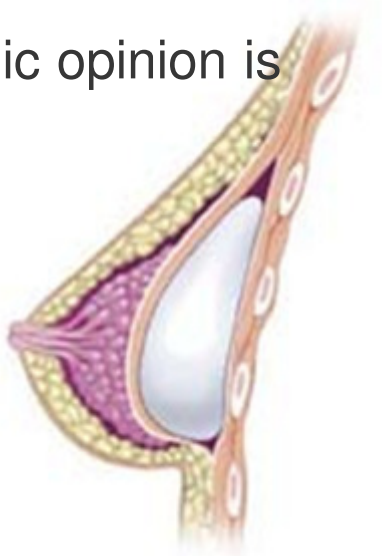
MEDICAL DEVICE REGULATIONS IN SOME GLOBAL MARKETS

	USA	Australia	Japan	EU	Canada
Regulatory body	FDA Food & Drug Administration	TGA Therapeutic Goods Administration	MHLW Ministry of Health, Labor and Welfare	CA Competent Authority	HC Health Canada
QMS standard	21 CFR Part 820 based on ISO13485	ISO13485	Ordinance 169-2004 based on ISO13485	ISO13485	ISO13485
QMS verification	FDA accredited parties	TGA	MHLW + sometimes 3rd party	Notified Body	Registrar
pre-market review	FDA 3rd parties	TGA	MHLW	Notified Body	HC
post-market compliance	FDA	TGA	MHLW	CA + NB	HC

3rd party

DEVELOPMENTS IN THE RECENT PAST: (R)EVOLUTION

Post P.I.P. (breast implants): politicians are nervous, public opinion is interested in medical devices, ….



- July 2012: IAF MD 9
  - International Accreditation Forum guide on medical device audits
    - Audit time increased significantly
    - More competences required from auditors
- Starting in 2012: Code of Conduct for Notified Bodies
  - Voluntary, but seen as ‘not yet sufficient’ by the Commission
    - Only 29 Notified Bodies (of 77) were able to sign this !!
    - qualification and competences for auditors
    - Time for audits and reviews
    - Unannounced visits
    - Auditor rotation
    - …

DEVELOPMENTS IN THE NEAR FUTURE: (R)EVOLUTION

Post P.I.P. (breast implants): politicians are nervous, public opinion is interested in medical devices, ….

- Joint assessment of Notified Bodies by Authorities/Commission
- 24 September 2013:
  - Recommendation of 24 September 2013 on the audits and assessments performed by notified bodies
    - Unannounced audits, sampling devices to be tested, private labelling/own brand labelling changed, ….
  - implementing regulation on designation and the supervision of notified bodies
    - Joint inspection by Authorities, investigation of competences, stricter designation, exchange between Authorities, …

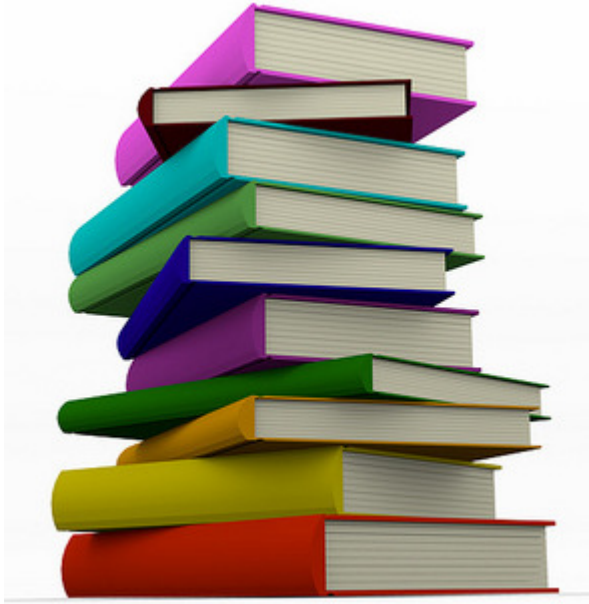
=> Already 4 NoBo's (of 80) closed last few months

DEVELOPMENTS IN THE NEAR FUTURE: (R)EVOLUTION

Post P.I.P. (breast implants): politicians are nervous, public opinion is interested in medical devices, ….

- April/Mai 2014 (?): new Medical Device Regulation will be voted by the European Parlement:
  - Totally rewritten, more control, more requirements
  - Many changes for all manufacturers and notified bodies. (including totally new approach for high risk medical devices)

Summing up…



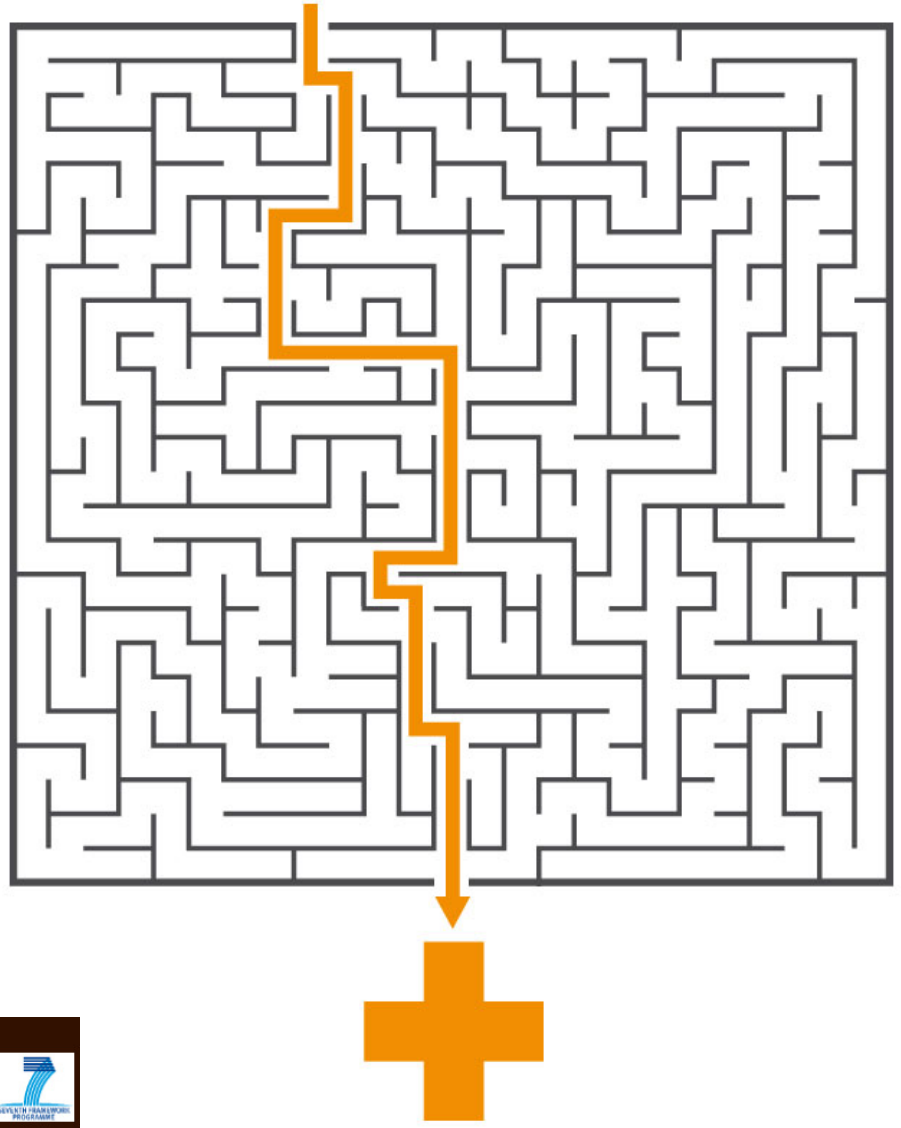
SUMMING UP…

- Choose and contact a Notified Body in an early stage
- Start Technical File and QMS in an early stage.
- CE marking, classification, … is not a choice.
- Choose a ‘respected’ Notified Body as he is your partner for long time.
- Foresee sufficient time, budget and resources (knowledge)

⇒ No CE certificate => no devices on the market !!!! Even if CE certificate is some days too late due to …

⇒ Incorrect certification: the company is responsible for their medical devices and the certification

Notified Bodies and the CE certification Process for Medical Devices



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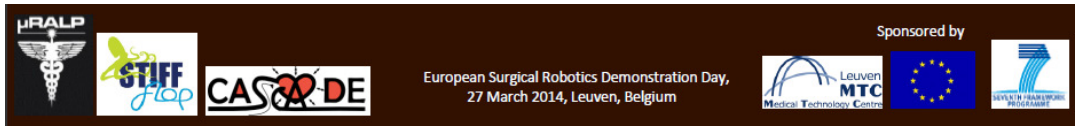

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