How to put a medical device on the European market

Think & Do

Consultant in Medical Device
Quality Management Systems and CE marking

Klappijstraat 29,
3294 Diest, Belgium
Content

- Placing devices on the EU market
- A medical device ?
- Manufacturers’ obligation
- Quality Management System versus CE
- How to get CE
- Timelines
- Tips & tricks
- New regulation
- Questions & Answers
Placing devices on the EU market

• European Economic Area – 1 single market
• Standardized requirements: safety, health and environmental
• Advantage for consumers and manufacturers
• No borders
• Directives for defence, food, toys, space, .., medical devices

• If they meet the requirements:
Placing devices on the EU market

- New product?
- Define the **intended purpose** of your product

- ‘intended purpose’ means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;
- Check it for the different directives
A medical device?

- ‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
  - investigation, replacement or modification of the anatomy or of a physiological process,
  - control of conception,
  and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

- Definition on IVD, AIMD
A medical device?

Intended use determines:

- applicable EU Directive(s)
- (patient) risks related to the product
- conformity assessment
- classification of the product
- manufacturing environment prerequisites
- ..... 

...all obligations for a manufacturer
A medical device

• Medical Device Directives:
  • 93/42/EEC for Medical devices, amended 2007/47/CE
  • 98/79/EEC for In Vitro Diagnostic devices
  • 90/385/EEC for active implantable devices

• Law:
  • KB 18 maart 1999, KB 10 maart 2009

• (New) April 2017: Medical device Regulation
  • In full implementation 2020
Manufacturers’ obligation

- To prove safety and performance of its device:
  - To prove and guarantee the performance and safety of the individual device during its lifetime
  - To prove that it fulfils the essential requirements (Annex 1 of the MD Directive 2007/47/EC)
  - To document its performance and safety in a technical file, maintained and available during the product lifetime.
  - To set up (manufacturing) processes to maintain this level of performance and safety.
Manufacturers’ obligation

• Medical Device Directive states:
  “A medical device manufacturer has to apply a quality management system”
  ✓ Standardize the product quality
  ✓ Standardize the processes
  ✓ Standardize the control
  ✓ Standardize the documentation
  ✓ ...implement processes to develop, manufacture, test, sterilize, pack, store, transport .. by which the (essential) requirements for the products are consistently met.
A manufacturer has to apply a Quality management system:
- ISO9001 – can be applied by any type of organization
- ISO13485 – Quality management System for Medical device manufacturers

The product has to carry the CE mark:
- CE Declaration of Conformity
- Product in compliance with Annex I of the Directive
- If the manufacturer has applied a QMS
How to get CE?

• Implement a Quality Management System
• Determine Conformity assessment route with the classification of your medical device
  • Use Annex IX of the Directive
  • Use Guidance documents to clarify
• Conformity assessment
  ➢ Class I: self declaration by manufacturer
  ➢ Class I sterile, Class I measuring function, Class IIa, Class IIb, Class III: CE after Notified Body evaluation
  ➢ IVD: List A and List B: CE after Notified Body evaluation
How to get CE?

• Major steps:
  o Implement QMS
  o Start documenting to establish the technical file
  o Application to Notified Body
  o Audit ISO13485 of the organization
  o Technical File Review
  o ISO certificate
  o CE certificate
  o ...start of monitoring....
Implement a Quality Management System

• Manage processes with QMS principles
• Standardize:
  – Plan – Do – Check – Act
  – From management to quality processes
  – Documented system: Procedures, instructions, policy
  – Record evidence: Analysis reports, test results, certificates, FMEA,...
Implement a
Quality Management System
Implement a
Quality Management System

• Requirements on documented procedures from ISO13485
  • 4.1.6 Validation of computer software
  • 4.2.3 Procedures for manufacturing, packaging, storage, handling, distribution, measuring and monitoring, servicing
  • 4.2.4 Control of documents
  • 4.2.5 Control of records
  • 5.6 Management review
  • 6.4.1 Monitoring of work environment
  • 7.3 Design & development
  • 7.4 Purchasing
  • 7.5.1. Production
  • 7.5.4 Servicing activities
  • 7.5.6 Validation of production processes, and application of software in production
  • 7.5.7 Validation of sterilization processes
  • 7.5.8 Identification
  • 7.5.9 Traceability
Implement a Quality Management System

- Requirements on documented procedures from ISO13485 (Continued)
  - 7.5.11 Preservation of product
  - 7.6 Control of monitoring and measuring devices
  - 8.2.1 Feedback
  - 8.2.2 Complaint handling
  - 8.2.3 Reporting to authorities
  - 8.2.4 Internal audit
  - 8.2.6 Monitoring and measurement of product
  - 8.3.1 Control of Non-conforming product
  - 8.3.3 Non-conforming product after delivery
  - 8.3.4 Rework
  - 8.4 Analysis of data
  - 8.5.2 Corrective Action
  - 8.5.3 Preventive action
Implement a Quality Management System

• Requirements on documented procedures from Medical Device Directive:
  • Quality manual, objectives, plans, records
  • Document management
  • Responsibility and authorities
  • Methods of monitoring, testing, verification, ..
  • Control of non-conform products
  • Design/Production control measures
  • Procedure test & control
  • Procedure market feedback
  • Procedure clinical evaluation
  • Procedure corrective actions
  • Procedure incident management
+ regulatory required procedures – from Commission Regulation Sep 2013.
Implement a Quality Management System

• Several more other documented requirements depending on the type of activities: risk management, maintenance, competence, service, cleanroom, ..

Continuously updates....

• New version of ISO13485: 2016, to applied before March 1, 2019
• New MDR
• Publishing by EU of guidance documents updates
  • Guidelines
  • Interpretative documents
Set up a technical file

- Content is defined in Annexe(s) of Directive
- To prove that medical device fulfils essential requirements (Annex I)
- Extent of technical documentation depends on classification, complexity, technology, type of products, applied processes (sterilisation, software, measuring functions, radiation..)
- Evidence of application of EU harmonized standards
- Documentation out of the development process
- Formally approved documents

(with support of an experienced consultant)
Application to a Notified Body

- Many companies start with this step....
- NB controlled by local competent authority
- Today: less than 40
- Technical experts in the area of your product
- Complex review processes
- Good collaboration is KEY – interaction between manufacturers and notified body is continuously expanding
Audit of QMS and Technical File Review

- Based on proposal of Notified Body
- ISO13485 stage1 audit, stage 2 audit
- Non-conformities
- Technical File review
  - Documentary
  - Technical review
  - Clinical review
Monitoring

• By internal control (internal audits)
• By Certification body ISO13485
  • At first product release
  • At least once a year
  • At manufacturers premises AND contractors
• By Notified Body
  • At least once every 3 years Technical File Review
  • On a change
  • Unannounced on manufacturing location— focus on product performance and safety – at least once every 3 years
Realistic timelines

- Normal timeframe to set up a quality management system: 6 months
- Normal timeframe to create technical file: 3 months if major evidence is available
- Normal timeframe for Notified Body/certification body between acceptance of proposal to certification: 6 – 9 months
Information sources

1. Local competent authority – FAGG: www.fagg.be
5. Medical device forums, working groups, .. http://www.imdrf.org/, http://www.team-nb.org/
Tips and tricks

• Look out for competent people (to support)
• Administrative work behind is significant
• Realistic timelines
• Use information sources (today !!) – monitor on a regular base

• Known.. There is no end...
New legislation

• Medical Device Regulation
  – Outcome of many years of work, after scandals
  – 565 pages
  – More requirements means more obligations for manufacturer
  – Unique device Identification
  – More control over supply chain
  – More requirements of Qualification of Quality Manager
  – .....
Questions & Answers

• Questions ??
• Support at
  Peter.frederickx@think-and-do.be