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CE-Marking a Robotic Medical Device

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The CE mark appended by the legal manufacturer indicates the conformity of the products with the provisions of the applicable directives

Medical devices* require a CE-mark before being placed onto the European market

1. What scrutiny are medical devices submitted to before they can be put into service and commercialised in Europe?
2. What are the expectations for a robotic medical device?
3. What clinical evaluation is expected to demonstrate safety and performance?
4. How do you demonstrate the acceptability of the benefit/ risk ratio?
5. What does compliant technical documentation look like?

* Excluding custom-made devices and devices intended for clinical investigation.

Medical devices and accessories - Definitions

COUNCIL DIRECTIVE 93/42/EEC provides the following definitions:

(a) ►**M5** 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, 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;

(b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

Directive 2006/42/EC on machinery

- MDD article 3:
  - Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC [...] shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to this Directive.
- 'machinery' means:
  - an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,
  - [...]
  - Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives.

- Mainly addressed by IEC 60601 testing.

What scrutiny are medical devices submitted to before they can be put into service and commercialised in Europe?

- Device classification
- Conformity route

- Demonstrate compliance with essential requirements

Classification of medical devices

Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX. [MDD]

- The device class is linked with the risk of the device
- The classification rules are based on different criteria, such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device.
- Annex IX lists 18 rules to guide classification
  - Non invasive devices – Rules 1, 2, 3, 4
  - Invasive devices – Rules 5, 6, 7, 8
  - Active devices – Rules 9, 10, 11, 12
  - Special rules – Rules 13, 14, 15, 16, 17, 18

- MEDDEV 2. 4/1 Rev. 9 June 2010 - Classification of medical devices
  http://ec.europa.eu/health/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf

Conformity routes

CONFORMITY ASSESSMENT PROCEDURES	CLASSES					
		Need NB				
ANNEXES	I	Is	Im	IIa	IIb	III
II – Full QMS						•
II – (exc. section 4. Examination of design)		•	•	•	•	
III – Tech doc review and test of design					•	•
IV – NB final test			•	•	•	•
V – Production QMS		•	•	•	•	•
VI – Final inspection and testing QMS			•	•	•	
VII - DoC	•	•				

Applicable to all medical devices

Irrespective of the class of the device, all devices must:

- meet the essential requirements,

  including the requirements regarding the information to be supplied by the manufacturer (Annex I of the Directive 93/42/EEC);
- be subject to the reporting requirements under the medical device vigilance system;
- be CE marked,

  except custom-made devices and devices intended for clinical investigation, in which case they should comply with the provisions of Annex VIII of Directive 93/42/EEC regarding the statement on devices for special purposes.

Technical documentation

- As a general rule, the documentation should cover the design, manufacture and intended operation of the product.
- If harmonised standards have been applied, presumption of conformity with the particular essential requirements covered by the standards is assumed.

- NB-MED/2.5.1/Rec5

  http://www.team-nb.org/documents/2010/Recommendation-NB-MED-R2_5_1-5_rev4_Technical_Documentation.pdf

- Guidance on Design-Dossier Examination and Report Content

  http://www.nbog.eu/resources/NBOG_BPG_2009_1.pdf

- International Medical Device Regulators Forum IMDRF/RPS WG/N13FINAL:2014

  http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140630-rps-nivd-toc.pdf

Annex X - Clinical evaluation

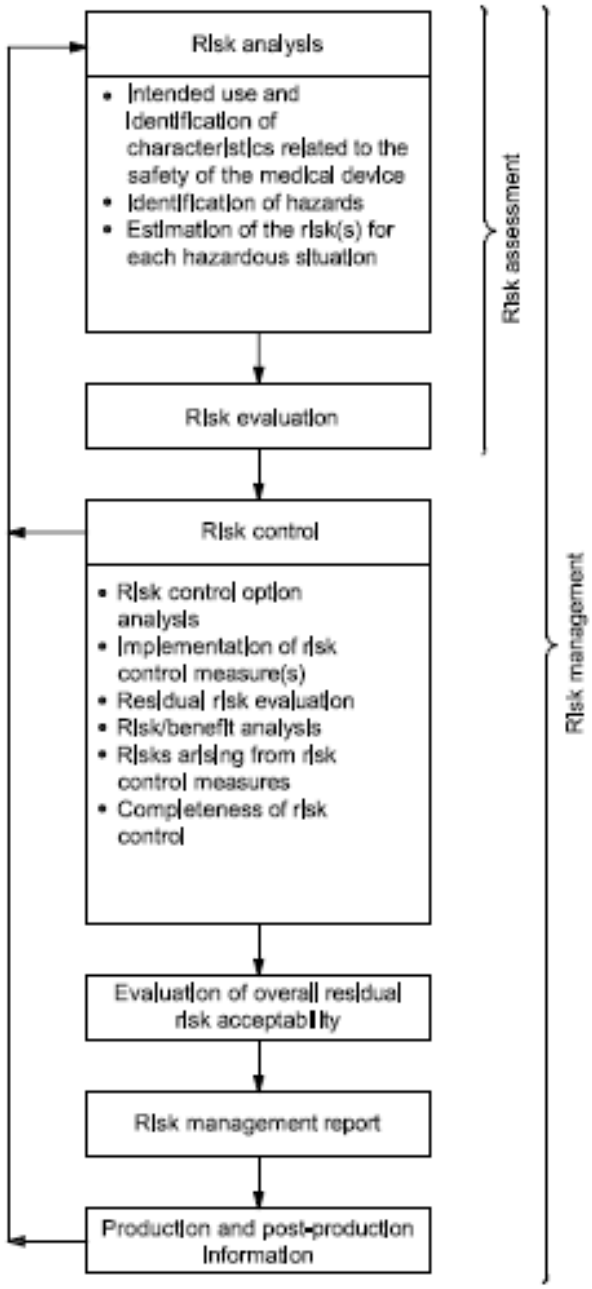
- As a general rule, confirmation of conformity with the requirements [...] must be based on clinical data
- The evaluation of this data ('clinical evaluation') must follow a defined and methodologically sound procedure based on:
  - Either a critical evaluation of the relevant scientific literature
  - Or a critical evaluation of the results of all clinical investigations made
  - Or a critical evaluation of the combined clinical data provided
- The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance
- Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated

MEDDEV. 2.7.1 Rev.3, December 2009 - CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

http://ec.europa.eu/health/medical-devices/files/meddev/2_7_1rev_3_en.pdf

Risk/ benefit analysis

- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices provides a process for managing risks associated with medical devices.
- Compliance with all the requirement clauses in this standard will ensure that general aspects of medical devices related to patient risk and safety have been addressed.
- All risks to be reduced to as low as possible.
- Medical benefits must outweigh the residual risks.
- If [...] evidence supports the conclusion that the medical benefits outweigh the overall residual risk, then the overall residual risk can be judged acceptable. Otherwise, the overall residual risk remains unacceptable.



Essential requirements and harmonized standards

- EN ISO 13485:2012
- BS EN 62366:2008/ IEC 62366-1:2015 Medical devices – Application of usability engineering to medical devices
- IEC 62304: 2006 – Medical device software – Software life cycle processes
- IEC 60601 family – Medical electrical equipment
- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
- ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good clinical practice

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