Introduction to medical devices

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What is a medical device?

- “medical device” means an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—
  - (a) is intended by the manufacturer to be used for human beings for the purpose of-
    - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
    - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
    - (iii) investigation, replacement or modification of the anatomy or of a physiological process, or
    - (iv) control of conception; and
  - (b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,
- and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;

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“medical device means” any product used alone or in combination

Intended to be used on humans for diagnostics, therapeutics or modifying anatomy or physiology

Excluding medicinal products (unless integral)

Medical device types

The 3 main types of medical devices and their associated Part in the UK MDR 2002 are:

- general medical devices: Part II of the UK MDR 2002
- active implantable medical devices: Part III of the UK MDR 2002
- in vitro diagnostic medical devices (IVDs): Part IV of the UK MDR 2002

You must meet the requirements in the relevant Part before your device can be placed in the market.

General medical devices

- Examples include
  - first aid bandage
  - hip prostheses
  - X-ray equipment
  - ECG monitors
  - heart valves
  - dental materials
  - spectacles
  - depressors

Silver wound dressing

Stethoscope

Pulse oximeter

Ultrasound imaging

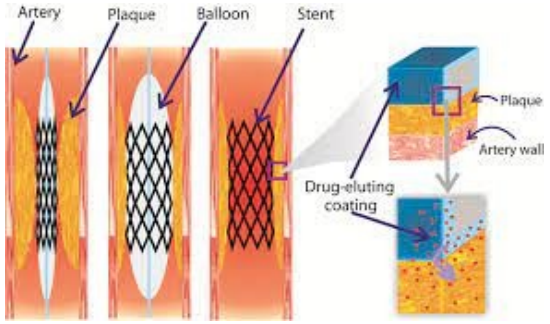
Hospital bed

Surgery robot

Active implantable devices

Powered implants or partial implants that are left in the human body. Examples include:

- implantable cardiac pacemakers
- implantable defibrillators
- implantable nerve stimulators
- bladder stimulators
- cochlear implants
- implantable active drug administration device
- catheters, sensors for item above
- Implantable active monitoring devices



In vitro diagnostic devices (IVDs)

This type of medical device is usually a:

- reagent
- reagent product
- calibrator
- control material, kit, instrument, apparatus
- equipment or system intended for use in vitro to examine specimens including blood and tissue donations from the human body
- More specific examples include blood grouping reagents, pregnancy test kits and Hepatitis B test kits.
- See further guidance on the legislation relating to in vitro diagnostic devices for further information.

What is a medical device? Intended use

- A statement defining the scope of the device. It may include:
  - Patient population
  - Operating environment
  - Functions (e.g. range of measurements or outputs)
  - Medical conditions
  - Indications and contra-indications
  - Who it is intended to be used by?

- Why does it matter?

What is a medical device? – Intended use

The Braun ThermoScan thermometer is indicated for intermittent measurement and monitoring of human body temperature for people of all ages. It is intended for household use only.

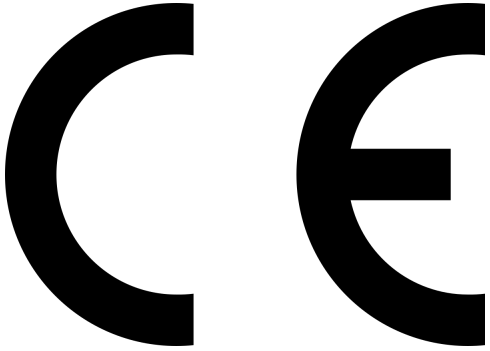
The Braun ThermoScan® PRO 6000 Ear thermometer is a clinical grade ear thermometer that in normal operation mode displays an estimate of oral temperature. It is indicated for the intermittent measurement of human body temperature in patients of all ages in a professional use environment.

The Medical Device Technical File

- Documents that demonstrate compliance with the regulations
  - Description, Drawings
  - Design, Calculations
  - Classification
  - Instructions for Use
  - Risk assessment
  - Quality management
  - Evidence for conformity with Essential Requirements
  - Manufacturing methodology
  - Clinical evaluation
  - Standards
  - Verification, Validation
  - Post market surveillance & vigilance
  - Etc.

EU Medical Device Directive 93/42/EEC

- Written into UK law via The Medical Device Regulations 2002
- Enables European trade of medical devices
- Medical devices must be CE marked before they are placed on the market
- CE marking demonstrates that the manufacturer has conformed with the regulations and their device is safe to be sold in Europe.



Why do we need regulations for medical devices?

- PIP Silicone breast implant
  - Used an industrial grade silicone instead of medical grade
  - Significantly high failure rates
  - Founder sent to prison for 4 years, fined €75k, facing multiple charges including involuntary manslaughter

- Johnson & Johnson metal-on-metal hip replacement
  - Poor wear characteristics
  - Released metal particles into the body (metallosis)
  - Implants required replacement after 5 years (typically should last 15 years)
  - Paid out $1bn

Key players for Regulation

EU commission

- Created the law

Competent Authority (CA)

- Legal authority to enact the law
- MHRA in the UK (1 per country)

Notified body (NB)

- Devolved responsibility from CA to carry out conformity assessments
- E.g. BSI, SGS etc.

Manufacturers

- Responsible and liable for ensuring their product complies with the regulations
- Must sign a Declaration of Conformity

What is relevant to medical devices?

- Medical Device Regulations 2002
  - Medical Device Directive 94/42/EEC
  - Active Implantable Medical Device Directive 90/385/EEC
  - In vitro diagnostic Medical Device Directive 98/79/EC
- Health & Social Care Act 2008 (regulated activities) Regulations 2014
- Health and Safety at work Act 1974
- Consumer Protection Act 1987
- Electricity at Work Regulations 1989
- Wiring regulations BS 7671
- Lifting Operations and Lifting Equipment Regulations (LOLER) 1998
- Provision and Use of Work Equipment Regulations (PUWER) 1998
- Ionising Radiation (Medical Exposure) Regulations (IRMER) 2017
- **… and many more depending on applications**

Essential requirements of a medical device - General

1. Benefits must outweigh risk
2. Must take into account state of the art
3. Must perform as intended by manufacturer
4. Performance must not be compromised over the lifetime of the device
5. Performance must not be compromised by storage and transport
6. Positive risk-benefit ratio for undesirable side effects

Essential requirements – Design and Construction

7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Devices with a measuring function
11. Protection against radiation
12. Requirements for medical devices connected to or equipped with an energy source
13. Information supplied by the manufacturer

Medical device classification (ISO 14971)

- Governed by intended purpose
- https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements#classification-devices
- For general medical devices and active implantable devices
- Level of risk depends on:
  - Duration of contact, degree of invasiveness, anatomy affected, active or not
- 4 classes
  - Class I – scales, wheelchairs, cervical collar
  - Class IIa – suction, ultrasound, dental filling
  - Class IIb – defibrillator, X-ray
  - Class III – drug eluting stents, intra-aortic balloon pump

Increasing level of risk

- 18 specific risk rules

  e.g. Rule 14 - All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.

Risk assessment (ISO 14971 – Annexe C)

Risk (of producing harm) = Hazard x Exposure

Probability of occurrence of harm. Consequences of that harm (severity).

Clinical investigation

- Medical device equivalent of clinical trials for medicine.
- An investigation involving at least one human to assess the safety and performance of a device
- Device does not require CE marking **but**
  - Letter of no objection from CA
  - Must be approved by an ethics committee
  - Device must be identifiable
  - Named responsible medical practitioner
  - Investigation plan
  - Statement of conformity with Essential Requirements

Clinical evaluation

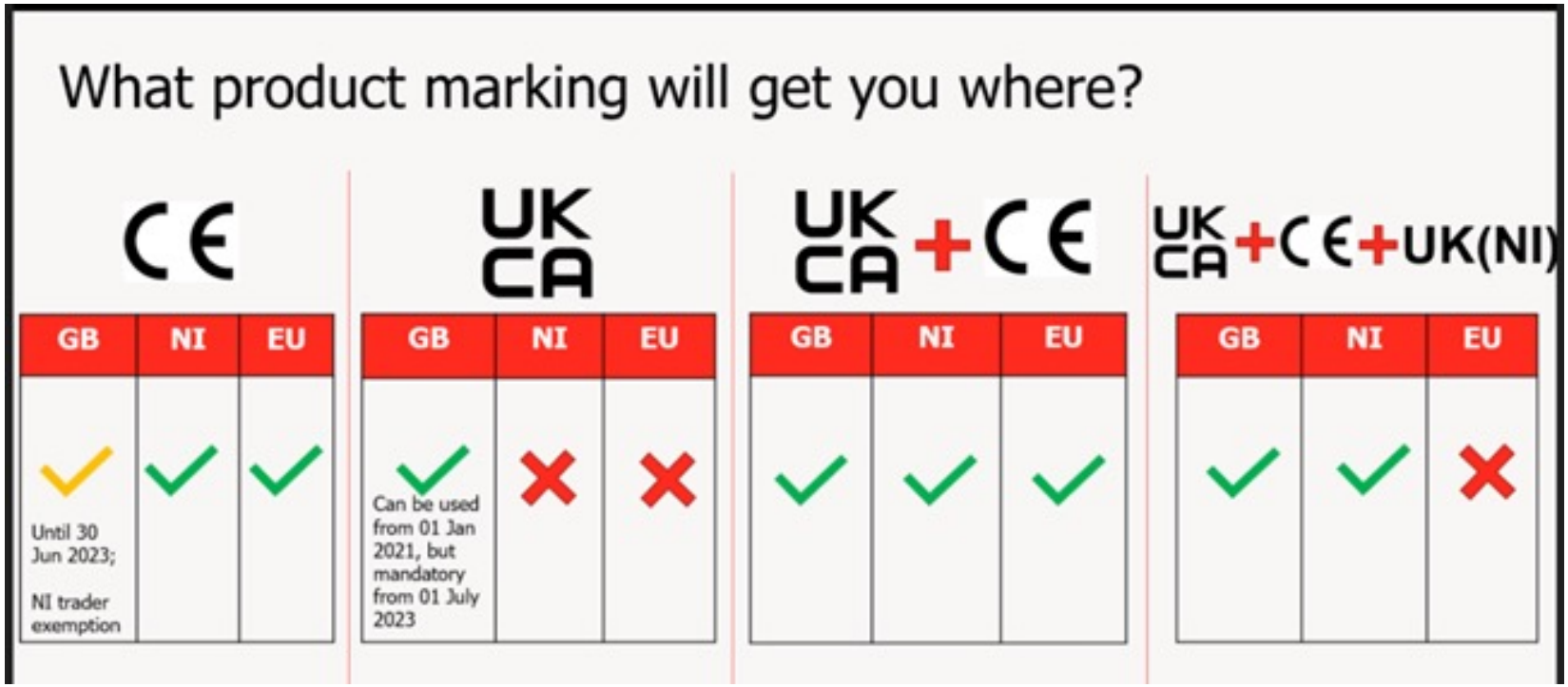
- A holistic assessment of all data related to the medical device to demonstrate conformity when used as intended.
  - Defined by information supplied by the manufacturer (instructions for use, labelling etc.)
- State of the art literature review
- Standards
- Results of clinical investigations
  - Did safety and performance outweigh any undesirable side effects?

Conformity Assessment

- A mark designating the manufacturers claim that their product meets the essential requirements of the relevant regulations (not just Medical Devices)

- Assessment depends on the class of the device
  - Class I – Manufacturer can self declare design and production
  - Class IIa – Manufacturer can self declare design, NB involved for production
  - Class IIb – NB involved for design and production
  - Class III – NB involved for design and production

Conformity Assessment



Post market surveillance & vigilance

- Once a device has been placed on the market, the manufacturer is still responsible for the device over its lifetime.

- Post market surveillance (Proactive)
  - System for monitoring device safety and performance
- Vigilance (Reactive)
  - Adverse incident reports to Competent Authority

- Field Safety Notice
  - Communication to users of actions to be taken to ensure safety and performance of device

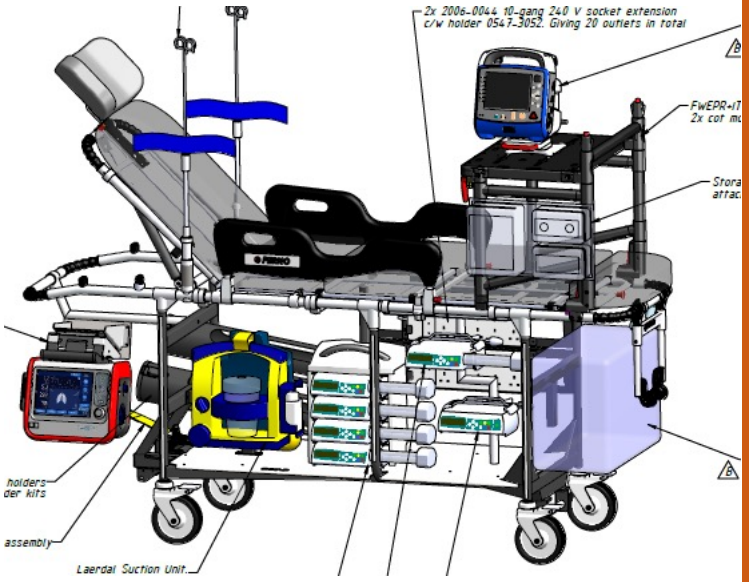
Custom made devices

- Manufactured for a named patient with a written prescription from a registered medical practitioner.
- Does not include mass produced products which are intended to be adapted.
- Does not require conformity assessments
- Still required to meet the provisions of UK MDR 2002.

- Examples: Prosthetics, orthotics, implants (designed for a specific patient)

Medical device systems

- Whereby CE medical devices are combined together within the limits of intended use.
- Does not require CE marking, but
  - Must ensure mutual compatibility of devices
  - Use a quality management system and develop light touch technical file
  - Supply information to the users incorporating instructions from original equipment manufacturers
- If outside of intended use, whole system must be CE marked.



What's a medical device?

1. A mobile app for processing ECGs
2. Toothbrush
3. Contact lenses
4. Autopsy saw
5. Pill box organiser
6. Wheelchair
7. Syringe driver

Summary

- Intended use of a medical device is not as easy as it sounds
- Beware of the number and type of regulations, directives that your device has to follow
- A medical device file is long to write up
- Risk assessment of a medical device is essential
- Manufacturer has duty to look after a medical device even after sale to hospital

Thanks for listening