Quality assurance for anthropometric equipment

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Tuesday 5th November
The key message for the QA session.

• Definition and Classification of Medical Devices
• 26\textsuperscript{th} May 2020 – enforcement day of the new MDR requirements...
• UNICEF Position
• The way ahead?
Definition of Medical Device.

“medical device’ means...

any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including; organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
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Classification of Medical Device.

- Article 51 points to Annex VIII
- Expect most if not all to be Class I or Class Im
- Ch II, para 3.3. Software, which drives a device or influences the use of a device, shall fall within the same class as the device.
- Notified Body involvement limited to technical aspects related to conformity of metrological requirements

- If there is an uncertainty on the correct classification of the product you should consult a national competent authority
New MDR 2017/745

• Comes into force on the 26th May 2020 – the transition period ends

• Some major changes that affect us all…
  • Notified Body involvement – Class 1 involvement now 80/20
  • Notified Body availability - [link](https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34)
  • Economic Operators
  • Additional data and reporting requirements
  • Benefit- Risk analysis
  • Active Post Market Surveillance
  • Eudamed and UDI
  • Supply chain - unannounced audits by your NB
UNICEF Position on Continued validity of current issued MDD Certificates.

• MDD Certificates can be issued up to 25th May 2020
• These MDD certificates will be valid until their original expiry date, or 26th May 2024, whichever is sooner.
• Manufacturers can continue to put MDD certified devices on the market up to and including 26th May 2024, assuming they continue to keep these certifications valid.
• It is important to note however that after 26th May 2020 no significant changes may be made to MDD certified devices. If a significant change is required, the device certificate must be migrated to MDR.
The Way Ahead

• Suggest you engage as soon as possible with your NB to determine if they will transition to the new MDR and codes and search out the guidance available in the EU resources.

• EUDAMED – Get registered as soon as the database is available use the UDI for new devices, remember your Importer, Authorised Rep all have to be registered seperately and you are required to record who you deliver products to

• Review your current QMS to ensure the new MDR requirements are captured i.e. Data capture and management, Active Post Market Surveillance, etc.
Thank You
### Bodies

**Search criteria:**

- **Legislation:** Regulation (EU) 2017/745 on medical devices
- Procedure / Article or annex:
  - ALL
- Products:
  - ALL
- Horizontal technical competence:
  - ALL

**Search**

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