Medaval Device Registration

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Summary

This document provides standardised description requirements for medical devices.

- Standard details for all medical measuring devices
- Specific details for Blood Pressure Monitors
- Specific details for Blood Glucose Meters
- Details for Blood Pressure Cuffs
- Suitable for device descriptions in Clinical Evaluation Reports prepared in accordance with MEDDEV 2.7/1 revision 4.
- In compliance with Council Directive 93/42/EEC as amended by directive 2007/47/EC
- Required supporting documentation specified.
- Standardised descriptions to ensure that all requirements are provided.
- Facilities to extend lists to include new and innovative features

Equivalence and Validation

- Suitable for equivalence comparisons in accordance with MEDDEV 2.7/1 revision 4
- Core measurement-critical items indicated as Technical, Clinical or Biological, in accordance with MEDDEV 2.7/1 revision 4
- Standardised descriptions ensure that equivalence comparisons are clear.
- Critical core items identified so that data and documentary evidence required for equivalence can be provided at the outset.
- Identity, Features and Accessories indicted so that requirements to identify device differences can be provided at the outset.

