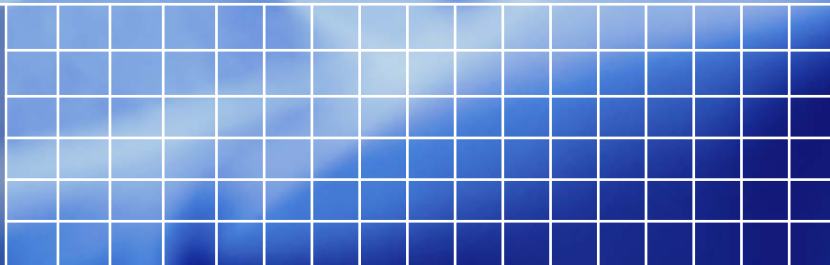


Medical Device Regulation 2017/745 Clinical Evaluation Report: Generalities

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Medical Device Regulation 2017/745 Clinical Evaluation Report: Generalities

What is clinical evaluation?

Clinical evaluation is a methodologically sound ongoing procedure to collect, appraise and analyse...

Sources of clinical data

| Clinical Data Source | Manufacturer's Device | Equivalent Devices* |
|------------------------|-----------------------|---------------------|
| Published Data | | |
| Clinical Investigation | | |
| ... | | |
| | | |
| | | |
| | | |

Benefit/Risk ratio

The clinical evaluation demonstrates that...

When clinical evaluation is required

The requirements for clinical evaluation apply to...

Clinical evaluation and risk management

Risk management and clinical evaluation must be...

