

ER #	Scope
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1	Risk Reduction & Acceptable Risk/Benefit
2	Safety and Risk Controls
3	Intended Performances
4	Lifetime of the Device
5	Transportation & Storage
6	Side-effects must Constitute Acceptable Risk
6a	Clinical Evaluation
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8	Infection & Microbial Contamination
9	Construction & Environmental Properties
10	Device with a Measuring Function
11	Protection Against Radiation
12	Devices with an Energy Source
13	Information Supplied by the Manufacturer

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Kathleen Armour



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