

ER #	Scope
Part I – General Requirements	
1	Risk Reduction & Acceptable Risk/Benefit
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3	Intended Performances
4	Lifetime of the Device
5	Transportation & Storage
6	Side-effects must Constitute Acceptable Risk
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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

# Essential Requirements Checklist Medical Device

**Yi-Tong Ma**



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