

## Comparison MDD & MDR

Essential Safety and Performance Requirements

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ESSENTIAL REQUIREMENTS ANNEX I 93/42/EEC	GENERAL SAFETY AND PERFORMANCE REQUIREMENTS ANNEX I 2017/745	REMARKS	MY COMMENTS
<p><b>General Requirements</b></p> <p>1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.</p> <p>4. The characteristics and performances...</p>	<p><b>CHAPTER I General Requirements</b></p> <p>1. Devices shall achieve...</p>		

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<p><b>This shall include:</b></p>	<p>2. The requirement in this Annex to reduce risks <b>as far as possible</b> means...</p>	<p>As far as risk reduction is concerned, it is <b>now</b> clarified that...</p>	

