

# Download File PDF Medical Devices Essential Principles Checklist

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Industry Technical Documentation for Demonstrating Conformance to the Essential Principles of Safety and Performance of Medical Devices (ESSEDP)  
Task Group 1 Final Document GHFP 902.1011.2007

Essential Principle	Applicable to the Device?	Method Used to Demonstrate Conformance?	Method Reference?	Reference to Supporting Controlled Documents?
<b>General Requirements</b>				
1.1 - Medical devices should be designed and manufactured in such a way that when used under the conditions and for the purposes intended and, where applicable, by virtue of the intended knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their 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.				
1.2 - The relations adopted by the manufacturer for the design and manufacture of the device should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risks associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the general case listed:				

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