

ESSENTIAL SAFETY AND PERFORMANCE REQUIREMENTS

Comparison Between In Vitro Diagnostic Medical Devices Directive 98/79/EC
and
In Vitro Diagnostic Regulation (EU) 2017/746

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Essential Requirements Directive 98/79/EC	General Safety and Performance Requirements Regulation 2017/746	Applicable Not applicable
<p>General Requirements</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, directly or indirectly, [...]</p>	<p>CHAPTER I General Requirements</p> <p>1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of [...]</p>	

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Essential Requirements Directive 98/79/EC	General Safety and Performance Requirements Regulation 2017/746	Applicable Not applicable
3. The devices must be designed and manufactured in such a way that [...]	See 4 (General Requirements) and [...]	