

ESSENTIAL SAFETY AND PERFORMANCE CHECK LIST

Medical Devices Regulation 2017/745

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Medical Devices Regulation 2017/745

Generalities

Medical devices can only be placed on the European Market if they satisfy a set of criteria called “General Safety and Performance Requirements”, as set out in...

Why is it recommended to have a General Safety and Performance Requirements Check List ?

...

The General Safety and Performance Requirements Check List shall be a controlled document.

...

Applicability of the General Safety and Performance Requirements

...

Method(s) used to demonstrate conformity

...

Reference to Standards or Common Specifications used

...

Evidence to demonstrate compliance

...

Using Annex Z of harmonized standards*

...

MEDICAL DEVICE REGULATION 2017/745 GENERAL ESSENTIAL SAFETY AND PERFORMANCE REQUIREMENTS **CHECK LIST TEMPLATE**

Name of device	
Name and Address of the manufacturer:	
Model number:	
Classification:	
Prepared by:	
Date:	

1. Document History



2. Readers Guidance

Below is a description of the individual columns in the Essential safety and performance requirements Checklist:

...

	Applicability N/A	Reference of Applicable Standards (ref, date, section)	Standards Applied or other Methods/docu- ments Applied <div>Justification why GSPR not applicable</div>	Document ID and Location
General Requirements				
1. ...				
2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.				
3. ...				