

AKRA TEAM TEMPLATES

Your key to success

AKRA TEAM offers many high-quality templates for medical device manufacturers.

The templates are based on years of experience in conformity assessment procedures. They provide not only content from the respective regulatory requirements, but also specific suggestions to draw up the content as well as pre-written text passages which can be easily adapted to your needs.

As such, they are a sound foundation for drawing up required documents for the Technical Documentation to be submitted to the Notified Body.

Benefits

- Fast and efficient creation of key documents for your Technical Documentation
- Reduced risk of deficiencies
- Higher success during conformity assessment procedures

Pricing

Template	Version	Pages	Net Price	Net Bundle Price	
Clinical Development Plan	2.2	12	500 €	3,500 €	
Clinical Evaluation Plan	2.2	87	1,500 €		
Clinical Evaluation Report	2.6	106	2,500 €		
Literature Search Protocol: State of the Art	2.2	22	500 €	800 €	
Literature Search Report: State of the Art	2.3	14			
Literature Search Protocol: Safety & Performance	2.2	18	500 €		
Literature Search Report: Safety & Performance	2.3	13			
Post Market Surveillance Plan (PMS Plan)	2.2	21	1,000 €	2,000 €	2,500 €
Post Market Clinical Follow-Up Plan (PMCF Plan)	3.2	17	500 €		
Periodic Safety Update Report (PSUR)	2.1	22	1,000 €		
Summary of Safety and Clinical Performance (SSCP)	2.6	37	1,000 €		
Regulatory Strategy Plan	1.1	20	500 €	N/A	

Participants of AKRA TEAM training will receive a **5% discount** for templates presented during the training.

Purchase Order Form for Templates

*Required fields

Company Name*	<input type="text" value="Name of the company"/>		
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☐ I have participated in the following AKRA TEAM training courses:

<input type="text" value="Date / Topic of the training"/>

Templates

Select here	Template and Document ID	Net Price	Net Bundle Price	
<input type="checkbox"/>	Clinical Development Plan AT TEMPLATE 019_CDP_Version 2.2	500 €	3,500 €	
<input type="checkbox"/>	Clinical Evaluation Plan AT TEMPLATE 020_CEP_Version 2.2	1,500 €		
<input type="checkbox"/>	Clinical Evaluation Report AT TEMPLATE 021_CER_Version 2.6	2,500 €		
<input type="checkbox"/>	Literature Search Protocol: State of the Art AT TEMPLATE 024_LSP SOTA_Version 2.2	500 €	800 €	
<input type="checkbox"/>	Literature Search Report: State of the Art AT TEMPLATE 026_LSR SOTA_Version 2.3			
<input type="checkbox"/>	Literature Search Protocol: Safety & Performance AT TEMPLATE 023_LSP Safety & Performance_Version 2.2	500 €		
<input type="checkbox"/>	Literature Search Report: Safety & Performance AT TEMPLATE 025_LSR Safety & Performance_Version 2.3			
<input type="checkbox"/>	Post Market Surveillance Plan (PMS Plan) AT TEMPLATE 027_PMS Plan_Version 2.2	1,000 €	2,000 €	2,500 €
<input type="checkbox"/>	Post Market Clinical Follow-Up Plan (PMCF Plan) AT TEMPLATE 028_PMCF Plan_Version 3.2	500 €		
<input type="checkbox"/>	Periodic Safety Update Report (PSUR) AT TEMPLATE 029_PSUR_Version 2.1	1,000 €		
<input type="checkbox"/>	Summary of Safety and Clinical Performance (SSCP) AT TEMPLATE 030_SSCP_Version 2.6	1,000 €		
<input type="checkbox"/>	Regulatory Strategy Plan AT TEMPLATE 018_Regulatory Strategy Plan_Version 1.1	500 €	N/A	

Date*

Signature* _____

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