

Component – Qualification

MAQUET Cardiopulmonary AG
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Company name	
and address	<hr/> <hr/> <hr/> <hr/>

Component name¹	Vendor part. no.	MAQUET part no.

¹ Please attach component specifications

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Where the answer is Yes/No or multiple choice, please tick the box with the applicable response

1	What is the exact intended use of the product?		
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2	Is the product CE marked according to MDD 93/42/EEC ?	YES	NO
	If "YES" please attach a copy of the CE certificate and the declaration of conformity for the device.		
3	If the product is not CE-marked, please attach specifications, like drawings, material specifications including biological and toxicity tests depending on the intended use (USP, ISO 10993)		
4	Please state the classification of the device according to Annex IX of MDD 93/42/EEC		
	Class I	Class IIa	Class IIb
			Class III
5	Is the product a commercially available medical device on the US-market ?	YES	NO
	If "Yes" please provide the "K" number for the 510(k) and attach a copy of the clearance letter with Summary of Safety and Effectiveness.		
	K-number:	<hr/>	
	Is the product a preamendment device (commercially available before May 28, 1976) on the US market ?	YES	NO
	Is the product listed with US FDA ?	YES	NO
	If "YES" please attach a copy of the device listing form FDA 2892.		
6	What is the maximum Bio Burden ?		CFU
7	What is the maximum LAL (acc. to USP) ?		IU
8	Is the product manufactured in a clean room ?	YES	NO
	If "YES", in what class?	Class 10000	Class 100000
			Other

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	If "NO", is it manufactured in a controlled area where the cleanliness of the product is not threatened ? Please give a brief description: _____ _____ _____				
9	How is the product packaged for transport to protect its cleanliness ? _____ _____				
10	Is the device acc. to its intended use, to be used in conjunction with other devices or equipment ?	Not applicable	YES	NO	
	If "YES" has it been established that the combination is safe and effective and that the combination does not affect the safety and performance of the combined devices / equipment ?		YES	NO	
	If "NO", is there labelling to this effect accompanying the device		YES	NO	
11	Can the device be sterilized with EO ?			YES	NO
	If "YES", please indicate if max. limits exist for the following sterilization parameters:				
	Temperature:	YES	NO	If "YES", value:	
	Other parameter:	YES	NO	If "YES", value:	
	Can the device be sterilized with another sterilization method ?			YES	NO
If "YES", please indicate the method: _____					
12	Are there special instructions relevant to storage and assembly ?			YES	NO
	If "YES" please describe these instructions: _____ _____				
13	Is the product :	sterile	unsterile		
	If "sterile" is there a determined shelf life for the device ?			YES	NO

	If "YES", please indicate the period of time: _____		
	If "unsterile", is there a shelf life for the device ?	YES	NO
	If "YES", please indicate the period of time: _____		
	If "sterile", is the device compatible for further ETO sterilization ?	YES	NO
	If "YES", please give the number of applicable cycles:	1 cycle	2 cycles
		more	
	If "unsterile", is this device compatible for several ETO sterilization cycles ?	YES	NO
	If "YES", please give the number of applicable cycles:	1 cycle	2 cycles
		more	
14	Are there special instructions concerning warnings and contra-indications?	YES	NO
	Please attach a copy of the instructions for use/external labeling as well as another other marketing material.		
15	Is each individual device provided with an instructions for use ?	YES	NO
16	Does the product contain Natural Rubber Latex (21 CFR 801) ?	YES	NO
17	Notice: _____ _____ _____ _____ _____		
18	<p>The signer ensures</p> <ul style="list-style-type: none"> that Maquet Cardiopulmonary AG will be informed at once of problems relating to product quality and product security like corrective actions and recalls. that Maquet Cardiopulmonary AG will be provided with an advance notice of any update/revision/change to the device. <p>Signature: _____ Date: _____</p> <p>Name: _____ Title: _____</p>		

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