



Questionnaire - Good Distribution Practice Medical for Medical Device (GDPMD)(MDA, Malaysia)

The details provided within this questionnaire will be used to provide you with a quotation for the provision of Certification International's assessment and certification services.

The questionnaire shall be signed by a senior member of management who has the authority to verify and confirm that all of the details are accurate.

Organisation Details			
Organisation name	[REDACTED]		
Main address of site to be certificated	[REDACTED] [REDACTED] [REDACTED] [REDACTED]		
Site address (if any)	[REDACTED] [REDACTED] [REDACTED] [REDACTED]		
Contact Name	[REDACTED]		
Position	[REDACTED]		
Telephone (Office)	[REDACTED]	Telephone (Mobile)	[REDACTED]
Facsimile	[REDACTED]		
Email address	[REDACTED]		
Website address	[REDACTED]		
Total number of employees in organisation to be certified			[REDACTED]
Scope Details			
Please state your desired scope of certification. (This will be reviewed during the Initial Audit)	[REDACTED]		
Have you or will you use a consultant to develop your managements system(s)? Yes <input type="checkbox"/> No <input type="checkbox"/>			
If Yes; please provide details	[REDACTED]		
The roles of your organization	<input type="checkbox"/> Importer <input type="checkbox"/> Distributor <input type="checkbox"/> Authorized Representative (AR) If Importer or/ and Distributor is selected only, please state the AR name and address of the Medical Device(s) in Malaysia? (Please use attachment if necessary) [REDACTED] [REDACTED] [REDACTED]		
Medical Device Classification	<input type="checkbox"/> Class A <input type="checkbox"/> Class B <input type="checkbox"/> Class C <input type="checkbox"/> Class D		
Target date to commence Stage 1 audit	[REDACTED]		

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GDPMD Scope Business Factors				
No	Factors	1	2	3
1.	Does your company business activities involved outsourced parties/ processes?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
		If Yes, Please name the outsourced parties/ processes: <div style="background-color: #cccccc; height: 40px; width: 100%;"></div>		
2.	Does your company business activities involved secondary assembly including repackaging?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
3.	How is the company compliance status to legal requirements?		Good Regulatory Compliance <input type="checkbox"/>	Poor Regulatory Compliance <input type="checkbox"/>
4.	Is the medical device distributed in sterile state?		No <input type="checkbox"/>	Yes <input type="checkbox"/>
5.	Does the organization provide servicing/ maintenance service to the medical device distributed to the customers/ users?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
6.	Is the medical device distributed include active medical device (e.g. operated by electricity)?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
7.	Does your business involved installation, testing and commissioning of active medical devices?		No <input type="checkbox"/>	Yes <input type="checkbox"/>
8.	Is there any special storage required for the medical devices (e.g. under certain controlled temperature)?		No <input type="checkbox"/>	Yes <input type="checkbox"/>
9.	How would you describe the overall complexity of your processes (based on level of training needed)?	Minimal training required <input type="checkbox"/>	Some structured training required <input type="checkbox"/>	Formal education or training required <input type="checkbox"/>
10.	Do many staff perform the same activity?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
11.	Do you have a large site (or sites) with low numbers of employees (e.g. large factory area, large construction area etc)?		No <input type="checkbox"/>	Yes <input type="checkbox"/>
12.	<u>OR</u> Do you have a very small site for number of employees (e.g. office complex only)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

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No	Factors	1	2	3
13.	Is your business carried out over many buildings or sites?		No <input type="checkbox"/>	Yes <input type="checkbox"/>
14.	Is a proportion of staff travelling whilst reporting in to a central location, e.g. sales personnel, service personnel etc.?	Some <input type="checkbox"/>	No <input type="checkbox"/>	
15.	Is your product or service subject to a high degree of regulations (e.g. aerospace, food, drugs, accountancy etc.)?		No <input type="checkbox"/>	Yes <input type="checkbox"/>
16.	Is the organisation multi-lingual such that translation would be required for the audit process?	No <input type="checkbox"/>	Yes – Some areas <input type="checkbox"/>	Yes - All areas <input type="checkbox"/>
17.	How long have you been operating the current management system?	> 3 years <input type="checkbox"/>	<= 3 years <input type="checkbox"/>	
18.	How long have you had the current management system certificate in place?	> 3 years <input type="checkbox"/>	Not applicable or <= 3 years <input type="checkbox"/>	

Please attach the relevant continuation page(s) for the standards to be covered by certification

Name:

Signature:

Position:

Date: