

2. QUALITY SYSTEM OF THE MANUFACTURER

	YES	NO
Are You obliged to work by good manufacturing practice (GMP)?	<input type="checkbox"/>	<input type="checkbox"/>
Who inspects Your company against GMP rules?		
Have You a certified quality management system by ISO 9001:2008 and /or ISO 13485:2003 norm?	<input type="checkbox"/>	<input type="checkbox"/>
If YES, attach a copy of Your certificate and move to chapter 3.	enclosed	
If NOT, are You planning on getting certified?	<input type="checkbox"/>	<input type="checkbox"/>
When?		
Do You have an organizational chart of Your company?	<input type="checkbox"/>	<input type="checkbox"/>
Do You have specifications and written standard operating procedures (SOPs) for products that we purchase from Your company?	<input type="checkbox"/>	<input type="checkbox"/>
Do You maintain a list of Your approved suppliers?	<input type="checkbox"/>	<input type="checkbox"/>
Do You have input controls of materials/services, and are there records relating to that?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a possibility of follow up (traceability) from the input material, through a production process, to the final product?	<input type="checkbox"/>	<input type="checkbox"/>
Do You calibrate Your measuring equipment and are there records relating to that?	<input type="checkbox"/>	<input type="checkbox"/>
Are there records relating to customer claims?	<input type="checkbox"/>	<input type="checkbox"/>
Do You analyze causes of customer claims for corrective measures?	<input type="checkbox"/>	<input type="checkbox"/>
Can You provide records of final quality check findings for every batch of Your products?		
From Your Quality Control Department	<input type="checkbox"/>	<input type="checkbox"/>
From an independent Quality assessing institution	<input type="checkbox"/>	<input type="checkbox"/>

3. ASSESMENT OF THE MANUFACTURER

Are You willing to accept our representative for an announced assessment of Your quality system on Your company premises?	<input type="checkbox"/>	<input type="checkbox"/>
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For the manufacturer

Filled by: _____

Position: _____

Signature: _____

In _____ date _____