


FB-M 15-114		Test Item Characterization Sheet		
1. Edition 24.02.2021	Date of Change 10.09.2021	Version 1	Page 1 / 1	

Sponsor, address (as desired in the final report)		
Ship and bill to (if different)		
Sponsor's responsible person		
Requested test(s)		
Quotation No.		Order No.
Testing acc. to GLP?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Sponsor-specific limits		

Information about the test item	
Name of test item (exact product name)	
Article No.	
Batch No.	
Number of test items to be tested	

Total surface of test item	cm² per test item
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!!!! Total surface of test item necessary for testing of Cytotoxicity!!!!

If surface of testitem can't be calculated – e.g. textiles or powder - the necessary weight of testing will be determined by the laboratory

Additional information about test items or testing procedure			
Testing	<input type="checkbox"/> completely, <input type="checkbox"/> partial (please fill)	Validation Bioburden	Should be done? <input type="checkbox"/> yes / <input type="checkbox"/> no Already done? <input type="checkbox"/> yes / <input type="checkbox"/> no Project-No.: (if existing)
Type of material	<input type="checkbox"/> metal <input type="checkbox"/> polymer <input type="checkbox"/> silicone <input type="checkbox"/> ceramic <input type="checkbox"/> other:		
Regarding reprocessing, does the test item have contact with?	<input type="checkbox"/> Bones <input type="checkbox"/> Mucosa or		
Are parts of the test item soluble in water? If yes, which part and what kind of material?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
May the test item be disassembled (if necessary)?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
May the test item be cut in pieces (if necessary)?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Any biocidal properties? If yes, please specify.	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Are the test items sterile?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If not sterile: may the test item be steam sterilized at 121°C/ 134°C?	Yes: <input type="checkbox"/> 121 °C <input type="checkbox"/> 134 °C <input type="checkbox"/> No		
Handling of test items after testing is complete (return delivery will be additionally charged)	<input type="checkbox"/> Disposition by CleanControlling Medical <input type="checkbox"/> Return delivery		

Please send us the filled form together with the test items.

Please use the exact wording desired on the final report

Please use different sheets for different test items or testing procedures. Thank you.

Please use this button to clear the form