



## TEST ITEM DATA SHEET

All.1 MORD en Rev 2 del  
05/01/2023

Study Sponsor (Name and address)			
Name of Test Item / Device As it will be reported in the Test Report			
Nature of body Contact Rif Table A.1 ISO 10993-1 If applicable	<b>Surface MD</b> <input type="checkbox"/> Intact skin <input type="checkbox"/> Mucosal Membrane <input type="checkbox"/> Breached surface	<b>Ext communicating MD</b> <input type="checkbox"/> Blood path indirect <input type="checkbox"/> Tissue / bone / dentin <input type="checkbox"/> Circulating blood	<b>Implant medical device</b> <input type="checkbox"/> Tissue / Bone <input type="checkbox"/> Blood
	Contact Duration	<input type="checkbox"/> ≤ 24 hours	<input type="checkbox"/> > 24 h to 30 days
Surface area and thickness of the device or Weight of the device			
Physical appearance			
Code No.			
Lot No.			
Sterility <input type="checkbox"/> Sterile <input type="checkbox"/> Non-sterile			
Method of sterilization: _____		Sterilization Lot: _____	
Batch produced by (Name and address) if different from sponsor			
Date of Manufacture			
Date of Expiry / Valid up to			
Date of Retest			
Number of test items			
Storage conditions <input type="checkbox"/> Ambient (21 to 29°C) <input type="checkbox"/> Cool and dry (+2 to +8°C) <input type="checkbox"/> Frozen (< -10°C)			
Safety Precautions, if any			
Material safety data sheet attached		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Certificate of analysis		<input type="checkbox"/> Yes <input type="checkbox"/> No	
GLP management for the requested tests		<input type="checkbox"/> Yes <input type="checkbox"/> No	
In the case of non-destructive tests, the sample must be returned (shipping costs paid by the Customer)		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Any additional information (optional)			
Name of The Sponsor's Representative			
Signature and date			
To be filled by Lab4LIFE			
Numero di accettazione:		Verificato da:	