


FB-M 15-216		Test Item Characterization Sheet – Reprocessing & Sterilization		
Erstell.-Dat. 26.06.2023	Änd.Datum -	Version 0	Seite 1 / 1	

Sponsor (as requested in the report)	
Delivery and billing address (if deviating)	
Contact Person	
Offer no. (if available)	
Order no. (if available)	

Information about the test item (TI)	
Name of the TI (exact article description)	
Artikel No.	
Batch No.	
Materials of the Item	
Sampling area	<input type="checkbox"/> entire test item, <input type="checkbox"/> specific areas of the test item
Acceptance criteria	

Reprocessing - Cleaning	
Contamination solution (test soil)	<input type="checkbox"/> blood <input type="checkbox"/> with additional mucin <input type="checkbox"/> with additional bone meal <input type="checkbox"/> others:
Contamination	<input type="checkbox"/> by glove <input type="checkbox"/> by insertion/dipping <input type="checkbox"/> others: <input type="checkbox"/> in assembled state <input type="checkbox"/> in disassembled state
Drying time after contamination	hours
Precleaning	<input type="checkbox"/> yes <input type="checkbox"/> no (worst case)
Cleaning detergent	<input type="checkbox"/> Neodisher MediClean forte <input type="checkbox"/> Neodisher MediZym <input type="checkbox"/> others:
Neutralization (if applicable)	<input type="checkbox"/> Neodisher Z <input type="checkbox"/> Neodisher N <input type="checkbox"/> without neutralization <input type="checkbox"/> others:
Special equipment (e.g. for contamination or cleaning)	

Reprocessing - Disinfection	
Thermal (automated) disinfection	<input type="checkbox"/> A ₀ 3000 (90°C, 5 min) <input type="checkbox"/> A ₀ 600 (90°C, 1 min, for UK) <input type="checkbox"/> other parameters:
Manual disinfection	<input type="checkbox"/> standard (<i>E. faecium</i>) <input type="checkbox"/> High Level Disinfection (<i>M. terrae</i>) <input type="checkbox"/> Intermediate Level Disinfection (<i>S. aureus</i> , <i>P. aeruginosa</i> , <i>M. terrae</i>) <input type="checkbox"/> others:

Sterilization	
Sterilization parameters (Full cycle)	<input type="checkbox"/> 134°C, 5 min (EU) <input type="checkbox"/> 134°C, 3 min (UK/NL) <input type="checkbox"/> 132°C, 4 min (US) <input type="checkbox"/> 132°C, 3 min (worst case) <input type="checkbox"/> other parameters:
Lubrication before sterilization	<input type="checkbox"/> yes, with <input type="checkbox"/> no
Packaging	<input type="checkbox"/> paper/foil (double-wrap) <input type="checkbox"/> container with loading of kg <input type="checkbox"/> fleece with <input type="checkbox"/> envelop fold <input type="checkbox"/> parallel fold <input type="checkbox"/> other folding:
Contamination (if applicable)	<input type="checkbox"/> in assembled state <input type="checkbox"/> in disassembled state

Additional information – Typical use of the medical device

**Please send us the completed form with the test items.
Please use a new form for different test items or for each test.
Please provide the information as you need it in the final report. Thank you**