


FB-M 15-216		Test Item Characterization Sheet – Reprocessing & Sterilization		
Erstell.-Dat. 26.06.2023	Änd.Datum 08.07.2024	Version 1	Seite 1 / 1	

The information provided will be included exactly as it is in the final reports; subsequent changes will result in additional costs!

Please use different sheets for different test items and send us the filled form digitally if possible or at least together with the test items. Thank you very much.

Sponsor (as requested in the report)			
Delivery and billing address (if different)			
Contact Person			
Offer no. (if available)		Order no. (if available)	
Confirm. no. (if available)		Requested test(s)	

Information about the test item (TI)	
Name of the TI (exact article description)	
Artikel No.	
Batch No.	
Materials of Test Item	.
Sampling area	<input type="checkbox"/> entire test item <input type="checkbox"/> partial testing Total surface per test item: _____ cm ²
Acceptance criteria	

Reprocessing - Cleaning	
Clinical use, expected contamination	
Contamination solution (test soil)	<input type="checkbox"/> blood <input type="checkbox"/> with additional mucin (for mucous contact) <input type="checkbox"/> with additional bone meal (for contact with bone) <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 Special equipment (e.g. _____ for contamination or cleaning)
Precleaning	<input type="checkbox"/> yes <input type="checkbox"/> no (worst case) Disassembly for Cleaning <input type="checkbox"/> yes <input type="checkbox"/> no
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:

Reprocessing - Disinfection	
Thermal (automated) disinfection	<input type="checkbox"/> A ₀ 3000 (90°C, 5 min for EU) <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