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|--------------------------|------------------------------|---|---------------|--|
| FB-M 15-114 | | Test Item Characterization Sheet | |  |
| 1. Edition 24.02.2021 | Date of Change 25.06.2025 | Version 5 | Page 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, address (as desired in the final report) | | | |
| Ship and bill to (if different) | | | |
| Sponsor's responsible person (Reports are only sent to the specified persons/ distributors) | | | |
| Requested test(s) | | | |
| Quotation No. | | Order No. (if available) | |
| Testing acc. to GLP? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | (One of the options must be selected) |
| Information about the test item | | | |
| Name of test item (exact product name) | | | |
| Article No. | | | |
| Batch No. | | | |
| Number of test items to be tested per test (Define clearly for pool sampling) | | | |

!!!! Total surface of test item necessary for testing of Cytotoxicity and for extractions in according with DIN EN ISO 10993-12 !!!!

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

| | | |
|---|--|---|
| Desired parameters for testing of Cytotoxicity | Extraction <input type="checkbox"/> 24h <input type="checkbox"/> 72h | Inkubation <input type="checkbox"/> 24h <input type="checkbox"/> 48h <input type="checkbox"/> 72h |
| Total surface of test item | cm ² per test item | |

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 |
| Type of material | <input type="checkbox"/> metal <input type="checkbox"/> polymer <input type="checkbox"/> silicone <input type="checkbox"/> ceramic | Project-No.: (if existing) | |
| | <input type="checkbox"/> other: | | |
| 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 or be cut in pieces (if necessary)? | | <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? | | Yes: <input type="checkbox"/> <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 <input type="checkbox"/> Pick-up by Sponsor (If none of the options are ticked, we assume disposal by default) | |

Please use this button to clear the form