eurofins | Medical Device Testing

Test Item Data Sheet for Medical Devices

****Important****

- *Please provide the following information EXACTLY as you would like it to appear in the Final report(s)/Test Report(s).*
- *Please fill out one form for each sample.*
- *Grey-shaded boxes and fields marked in **RED** are mandatory information.*
- *Name and characterization should identify the test item univocally; unavailable information can be indicated as 'N/A'.*
  ISO 17025 Test reports are reissued only in case of correction of errors and entry of information / data omitted available at the time of the tests. It is not possible to reissue a Test Report under ISO 17025 accreditation when the name / trademark of the analyzed product has changed without re-testing.
- *For tests conducted under ASCA Pilot Program Accreditation, Attachment A of FDA's 2020 Biocompatibility Guidance is used to ensure that the types of biocompatibility assessments recommended by FDA are considered based on tissue type and duration of contact with the device. The ASCA Pilot for biocompatibility testing of medical devices does not include certain types of devices that require customized sample preparation and/or testing methodologies, or absorbable and in situ polymerizing devices, liquid devices, creams, gels, hydrogel devices, and devices containing nanomaterials. The testing is performed on the finished device and only tissue contacting components (direct and indirect) are included in the test sample.*
- *For any further information please contact: EUROFINS TECHNICAL STAFF: DG_CIT005_StaffMEDBiolab@bpt.eurofinseu.com or call our operator at +39 02 25 07 15 1*

1. Study Sponsor, Study Monitor & Submission Markets

(as desired in the Final Report/Test Report)

1.1. Sponsor	*Company name:* Click here to enter text *Address:* Click here to enter text	**1.2. Contact person**	*Name:* Click here to enter text *Phone:* Click here to enter text *e-mail:* Click here to enter text
1.3. Monitor *(Company & Address)*	Click here to enter text	**1.4. Contact person**	*Name:* Click here to enter text *Phone:* Click here to enter text *e-mail:* Click here to enter text
1.5. Quotation N.	Click here to enter text	**1.6. Purchase Order (P.O. No.)**	Click here to enter text
1.7. Send Invoice to	☐ Same as Sponsor ☐ Same as Monitor ☐ Other _____		
1.8. Final report(s) shall be sent to (if different from invoice)	☐ Same as Sponsor ☐ Same as Monitor ☐ Other Click here to enter text		

2. Regulatory compliance

2.1. Test performance according to the following accreditation/certification (select only one)

☐ **For in vivo studies, by selecting this checkbox, the Sponsor declares under its responsibility that no other studies of the same type have been already performed on the test item**

☐ ISO 17025 (if applicable) ☐ GLP (if applicable) ☐ No specific accreditation required

☐ Request NOT to issue the Test Report under ISO 17025 accreditation: the Test Report will be issued without Accredia logo (see Quotation -section "ISO/IEC 17025 ACCREDITED ACTIVITIES" for further details)

2.2. Regulatory reference and competent Authority Information on regulatory compliance: - please note that some accreditations may not be applicable to all tests requested; - Good Laboratory Practice (GLP) certification can only be applied to studies with regulatory purpose. For this reason, we ask you to specify in the field below the competent authority who requests the test to be performed according to GLP. For any further information on accreditation follow this link: http://www.eurofins.it/servizi/pharma/accreditamenti/accreditations.aspx or contact DG_CIT005_StaffMEDBiolab@bpt.eurofinseu.com	
Competent Authority: (mandatory for GLP activities)	☐ US-FDA FD&C Act [21 CFR 58] ☐ Korean FDA ☐ SWISSMEDIC ☐ MHLW - PMDA (JAPAN) ☐ Other: Click here to enter text
Regulatory reference: (mandatory for GLP activities)	☐ ISO 10993-1:2018 par.6.3.1 & B.4.5.2

3. Test Item Characterization

3.1. Name of the Test Item (PRODUCT NAME) to be used in the Report	Click here to enter text		
3.2. Batch. No. / Lot No.	Click here to enter text	**3.3. Sample code:**	Click here to enter text
3.4. Manufacturing date: *(e.g. dd/mm/yyyy)*	Click here to enter text	**3.5. Expiry Date:** *(e.g. dd/mmyyyy)*	Click here to enter text
3.5.1 If **expiry date is not available**, the Sponsor declares under its responsibility that samples are to be considered stable for the aim of the study for at least: Click here to enter text months from the date of ☐ manufacturing or ☐ receipt of sample in Eurofins.			
3.6. The sample has undergone aging?	☐Yes ☐No If **Yes,** add this information**:** Time point: Click here to enter text Temperature and Humidity: Click here to enter text		
3.7. Storage Conditions *(Temperature/ protection from light)*	☐Room Temperature ☐2-8°C ☐≤ - 20°C ☐≤ - 70°C ☐Other Click here to enter text *Please specify, if other* **Protection from light** ☐Yes ☐No		
3.8. Type of Material	☐Metal ☐Ceramic ☐Synthetic Polymer ☐Natural Polymer ☐Synthetic Elastomer ☐Natural Elastomer ☐Colorants ☐Other: Click here to enter text *Please specify, if other*		
3.9. Calculated Surface [cm²] or Mass [g]	Sample surface [cm²]: Click here to enter text ☐Per item ☐In total Sample surface in direct and indirect contact with the tissue(s) [cm²] : Click here to enter text ☐Per item ☐In total Sample weight (g): Click here to enter text ☐Per item ☐In total		
3.9.1. Thickness of the device (thinnest part < 0.5 mm?)	Click here to enter text	**3.9.2. Filling Volume (ml)**	Click here to enter text ml

3.10. Is the test item sterile?	☐ **Yes**, the test item is sterile Sterilization Date: Click here to enter text *(please indicate the sterilization procedure)* ☐Steam 121°C ☐Steam 134°C ☐EO ☐γ-Irradiation ☐Other Click here to enter text *Please specify, if other* ☐**No**, the test item is not sterile, please test non-sterile
3.11. Does the test item have a surface coating?	☐Yes ☐No Click here to enter text *If Yes, please specify kind of coating*
3.12. Handling Precautions	☐basic ☐other Click here to enter text *Please specify or send a safety datasheet*
3.13. Please indicate part to exclude from sample preparation (if any)	Please indicate which components have to be excluded. Click here to enter text Please indicate if there are components (e.g., electrical components) that should not be cut because cutting can expose materials that are not intended to have tissue contact during clinical use. Click here to enter text Please indicate the surface of previously unexposed parts to consider during sample preparation if in contact with the tissue(s) during clinical use Click here to enter text
3.14. Additional Information (e.g. on sample preparation)	Click here to enter text

4. Test Item Categorization

4.1. Description of Medical Device/ Clinical Use	Click here to enter text
4.2. Product Status	☐ Raw material ☐ Intermediate product ☐ Finished product as it is intended to be used clinically (for ASCA testing, included sterilization if applicable)
4.2.1 Representative sample selection If the product, given its size, cannot be fully tested	☐ Representative sample provided by the Sponsor (the submitted test article proportionally represents the final finished device). Please provide documentation describing the percentage of device that each sampling portion is taken from the final finished device and a schematic image to show where the representative portion is taken from the device. ☐ Representative sample is to be prepared by Eurofins following specific instructions. Please describe the instructions in the following field or provide documentation describing the instructions. [Describe] Click here to enter text ☐ Representative sample provided by the Sponsor but how the test article is selected by the Sponsor is unknown. (This will not be tested under ASCA).

4.3. Device ***(ISO 10993-1)***	**Surface device** ☐Skin ☐Breached or comprised surface ☐Mucosal membrane	**External communicating device** ☐Blood path, indirect ☐Circulating blood ☐Tissue / bone / dentin	**Implant device** ☐Tissue /bone ☐Blood
4.4. Duration of contact *(Contact with tissue(s))*	☐Limited (≤ 24 hours) ☐Prolonged (24 hours to 30 days) * ☐Permanent (> 30 days) *		
4.4.1. EXTRACT CONDITIONS INFORMATION	Does the device contain heat labile or heat sensitive materials (e.g., drugs, biomolecules, tissue-derived components) at 50℃? ☐ YES ☐ NO Does the device include materials (e.g., polymers) that has glass transition temperature or melt temperature lower than 50℃? ☐ YES ☐ NO		
4.5. Direct and indirect body contact *** (necessary *for tests conducted under ASCA Pilot Program Accreditation*)**			
4.5.1. Which parts of the product are in DIRECT contact with the body?	☐ All parts of the product ☐ Not Applicable ☐ Defined parts of the product. Identification of components with tissue contact: Click here to enter text Surface Area of parts per Item in DIRECT tissue(s) contact in Click here to enter text cm² *Please calculate the direct contact surface*		
4.5.1. Which parts of the product are in INDIRECT contact with the body?	☐ All parts of the product ☐ Not Applicable ☐ Defined parts of the product. Identification of components with tissue contact Click here to enter text Surface Area of parts per Item in INDIRECT tissue(s) contact in Click here to enter text cm² *Please calculate the direct contact surface*		

5. TEST CONDITION DETAILS

5.1. Required Test:			
Test code	**Test name**	**Normative reference**	**Test condition details**
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text

5.2. Additional information:	Click here to enter text

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6. Sample Return or Disposal

6.1. Disposal of sample after testing is complete	☐return* - unused only and dispose used ☐return* - all (not for Test Materials that were in contact with blood or with inoculated microorganism) ☐dispose – all

If not filled, sample(s) will be disposed by Eurofins

**Additional cost may be charged*

Prepared by

Date Click here to enter text

Sponsor's Study Coordinator Click here to enter text
(Title & name)