|  |
| --- |
| **CUSTOMER INFORMATION** |
| Application Date: |  |
| Company Name: |   | Tax Office / Number: |   |
| Company Address: |   |
| Authorized PersonName Surname: |   | Advisor Name Surname : |   |
| E-mail: |  | Phone No: |  |
| Test Item Storage Conditions |   | Sample Return Request: |  [ ]  Yes [ ]  No |
| Special Note: |   |
| If all analyses of the relevant sample in the offer will be performed, you can write the offer number: |   |
| **Additional Information** |
| **Printed Report Submission:** [ ]  Yes [ ] NoIs deemed to be accepted. E-signed reports will be sent to you via e-mail. If a printed report is requested, the Offer will be made for the amount specified in the Contract Terms . | **Report Language:** [ ]  Turkish [ ] English [ ] Turkish + EnglishIs deemed to be accepted. If the request comes after the report has been submitted to the laboratory, the fee per report will be determined in the amount specified in the Offer and Contract Terms .  |
| **How to Apply the Decision Rule?**[ ]  Simple Acceptance Rule [ ]  False Rejection (Manufacturer/operator rule) [ ]  False Acceptance (Consumer rule) |
| In case there is no legal obligation, relevant standard/specification or any preference by you, the simple acceptance rule will be used. Decision rule <https://www.nano-lab.com.tr/Content/1/Media/d01pr17-karar-kurali-kilavuzur07.pdf>from our website information you can get . |
| **SAMPLE/PRODUCT INFORMATION** |
| Product Name: |  | Material Type: |  |
| Reference: |  | Sent Number . Number of Items: |  |
| Lot Number: |  | Test Article Usage Information: (ISO 10993-1) |  |
| Product Classification / Rule (you can add) | [ ]  Class I[ ]  Class Is[ ]  Class I[ ]  Class IIa[ ]  Class IIb[ ]  Class III | Product Structure | [ ]  Blood Bag[ ]  Contains Medicine[ ]  Contains Nanomaterial / Ag[ ]  Contains CMR Material[ ]  Advanced Diagnostic Medical Product[ ]  Contains Coating | [ ]  Contains REACH limit specified material[ ]  Contains Biocidal Active Substance[ ]  Absorbable[ ]  Contains Endocrine Disrupting Material[ ]  Other:  |
| **Final Purpose of Use:** |  |
| Does the product contain any other substance other than polymer in the part that comes into contact with the body? [ ]  Ceramic [ ]  Metal [ ]  Other \*\* If it contains more than one material, mark them all. (Explain)If you select the Other option, please explain:  |
| Does the product contain more than one type of polymer in the body contact area? [ ]  No [ ]  Yes (Explain)\*\* If it contains more than one material, mark them all.If you select the Other option, please explain:  |

|  |
| --- |
| **EXTRACTION CONDITIONS** |
| Contact Time | [ ]  <24 Hours [ ]  24 Hours < 30 Days [ ] 30 Days-1Year [ ] 1-10 Year [ ]  >10 Year |
| **C Value** |  |
| Extraction Medium | [ ]  Polar [ ]  Semi-Polar [ ]  Non-polar [ ]  Other:  |
| Extraction Conditions: | [ ]  24±2 Hours at 37±1 C°[ ]  72±2 Hours at 37 ± 1 C° [ ]  72±2 Hours at 50±2 C°[ ]  24±2 Hours at 70±2 C°[ ]  1±0,1 Hours at 121±2 C° |
| Physical Properties of the Product | [ ]  Solid [ ]  Liquid [ ]  Gas [ ]  Gel [ ]  Aerosol |
| Extraction Type | [ ]  Exhaustive (Consumptive/Corrosive extraction ) | [ ]  Exaggerated(Exaggerated extraction ) | [ ]  Stimulated(Stimulated extraction ) |
| Number of Extraction Repeats | [ ]  Single ( Single) [ ]  Triple ( Triplicate ) |
| Have you performed a solvent compatibility assessment on your device?If "Yes", please explain. | [ ]  Yes [ ]  No  |

|  |
| --- |
| **REQUESTED TESTS**  |
| **“ISO 10993-18 – Table 4 Test Methodologies for Extractables and Leakables”** |
| **CHARACTERISTIC** | **DEVICE** | **METHOD** | **Vote** |
| \*Volatile Organic Compounds (VOC) | HS-GC/MS | In-house Method (ISO 10993-18, ISO 10993-12, ISO 10993-17) | [ ]  |
| \*Semi Volatile Organic Compounds (SVOC) | GC/MS | In-house Method (ISO 10993-18, ISO 10993-12, ISO 10993-17) | [ ]  |
| \*Non-Volatile Organic Compounds (NVOC) | LC/MS MS | In-house Method (ISO 10993-18, ISO 10993-12, ISO 10993-17) | [ ]  |
| \* Elemental Metals a | ICP-MS | In-house Method (ISO 10993-18, ISO 10993-12, ISO 10993-17, ISO 17294-1 & 2 ) | [ ]  |
| \* Anions b | Ion Chromatography (IC) | In-house Method (ISO 10993-18, ISO 10993-12, ISO 10993-17, TS EN 10304-1 ) | [ ]  |
| \*Identification/Structure Determination c | FTIR-ATR | In-house Method (ISO 10993-18, ISO 10993-12, ISO 10993-17, ASTM E1252 ) | [ ]  |
| *\* Marked analyses are included in our scope accredited by TÜRKAK according to TS EN ISO/IEC 17025:2017.**a The elements will be determined according to ICH HARMONISED GUIDELINE-GUIDELINE FOR ELEMENTAL IMPURITIES-Q3D(R1) “.****Note:*** *If there is another element other than these that you request, please specify.* *b Fluoride (F-), Chloride (Cl-), Nitrite (NO 2 -), Orthophosphate (PO 4 -3 ), Bromide ( Br - ), Nitrate (NO 3 -), Sulfate (SO 4 -2) anions will be determined.****Note:*** *If there is another anion other than the one you requested, please specify.* *c* ***Note:*** *Please specify the product material composition and the parts to be identified separately.*  |

|  |
| --- |
| **REQUESTED TESTS** |
| **Degradation Risk Assessment Report for Device Materials** |
|  | **CHARACTERISTIC** | **METHOD** | **VOTE** |
| 1 | Identification and quantification of degradation products from polymeric medical devices | TS EN ISO 10993-13 | [ ]  |
| 2 | Identification and quantification of degradation products from ceramics | TS EN ISO 10993-14 | [ ]  |
| 3 | Identification and quantification of decomposition products from metals and their alloys | TS EN ISO 10993-15 | [ ]  |
| 4 | Identification and quantification of degradation products from products other than Polymer, Ceramic and Metal Products | In-house method | [ ]  |

|  |
| --- |
| **REQUESTED TESTS** |
| **“ISO 10993-18– Table 5 Methodologies to assess the structural composition of medical device materials ”** |
| **CHARACTERISTIC** | **DEVICE** | **METHOD** | **VOTE** |
| Molecular Weight Determination\*\* | GPC-SEC | In-house Method (ISO 10993-13) | [ ]  |
| Differential Scanning Calorimetry Analyses\*\* | DSC | In-house Method (ISO 10993-13) | [ ]  |
| Thermogravimetric Analysis\*\* | TGA | In-house Method (ISO 10993-13) | [ ]  |
| Scanning Electron Microscope Surface Characterization \*\* | SEM | In-house method (ISO 10993-14, ISO 10993-15) | [ ]  |
| Crystal Structure Identification \*\* | XRD | In-house method (ISO 10993-14, ISO 10993-15) | [ ]  |
| [ ]  If you have a different test request for characterization , please specify.  |
| **\*\*Services are received from contracted institutions within the above service parameters.** |

|  |
| --- |
| **Do you need any of the following services? If yes, please tick the relevant box.** |
| Toxicological Risk Assessment (TRA) according to ISO 10993-17 for E&L data of ISO-10993-18\*\*\* | [ ]  Yes [ ]  No |
| Biosafety/Assessment Plan or BEP (ISO 10993-1)\*\*\* | [ ]  Yes [ ]  No |
| Biological Risk Assessment Report (ISO 10993-1)\*\*\* | [ ]  Yes [ ]  No |
| **\*\*\*For the above service parameters, external services are received from contracted institutions/individuals.** |

|  |
| --- |
| **PHOTOGRAPHS, IMAGES and DIMENSIONS OF THE FINISHED PRODUCT (Can be submitted as an attachment to the request form.)** |
|  |
| **Explanation:** |  |
| **Dimensions (cm):** |  |
| **PHOTOGRAPH AND DIMENSIONS OF THE AREA IN CONTACT WITH THE BODY (Can be submitted as an attachment to the request form.)** |
|  |
| **Dimensions (cm):** |  |

|  |
| --- |
| **SAFETY AND OTHER INFORMATION** |
| Risk and Security: | For samples that may harm the user, the environment or the device, the Risk and Safety Codes must be specified below. After the necessary precautions are taken, the sample whose harmful effects are eliminated is accepted for analysis.[ ]  I declare that the product does not contain flammable, explosive, etc. chemicals. |

GENERAL CONDITIONS

* The laboratory is not responsible for any incorrect analyses and services, delays, or additional/re-analyses based on incomplete/incorrect information declared by the customer regarding the sample.
* The shipping and transportation of the sample is the responsibility of the customer. Samples that do not arrive in appropriate conditions will not be recorded and the customer will be informed.
* In cases where the sample does not meet the sample acceptance conditions, the laboratory informs the customer by making a conditional acceptance/rejection decision. In cases where the information provided by the customer has the possibility of affecting the analysis result, the laboratory includes a disclaimer in the report.
* Unless a different application is requested, samples are stored for 15 days from the report submission date. At the end of this period, samples are destroyed and analysis objections are not evaluated after this period. Samples whose expiration date has expired within this period are destroyed without waiting for the required period.
* Analysis Reports are sent to the e-mail address with e-signature. For wet-signed reports, the "Send method" section specified above must be selected.
* In case of any revisions made with a request to change the sample information later, the fee per report will be charged at the amount specified in the Offer and Contract Terms .
* The report to be prepared cannot be used in judicial, administrative proceedings or for advertising purposes.
* The laboratory is not obliged to disclose confidential information or notify the customer when required by law.
* The requested analysis methods are specified in the offer and analysis requests are processed after the submitted offer is approved by you. The company that approves this form is deemed to have accepted the laboratory working conditions.

|  |  |
| --- | --- |
| **SAMPLE ACCEPTING CONDITIONS** | **Conformity Check (To be filled by Sample Acceptance.)** |
| Sample Arrival Date: |  |
| Sample Transfer Conditions: | [ ] Suitable [ ] Not Appropriate ………………………………………………………………………………………………………………………………………………………………… ) |
| Sample Quantity: | [ ] Suitable [ ] Not Appropriate ………………………………………………………………………………………………………………………………………………………………… ) |
| 1. Samples must be in their original packaging and labeled. | [ ] Suitable [ ] Not Appropriate ………………………………………………………………………………………………………………………………………………………………… ) |
| 2. The physical structure of the packaging must be intact, not leaking and unopened. | [ ] Suitable [ ] Not Appropriate ………………………………………………………………………………………………………………………………………………………………… ) |
| 3. All samples sent must have the same content, charge/serial number and packaging features, all analyses will be performed on the same samples. Products with deformed, scratched or engraved labels will not be accepted. Notes/writings other than the label will not be taken into consideration. | [ ] Suitable [ ] Not Appropriate ………………………………………………………………………………………………………………………………………………………………… ) |
| 4. Sample Acceptance Status: | [ ] Acceptance [ ] Rejection …………………………………………………………………………………………………………………………………………………………… ) |
| Observations on the Sample: |  |
| I accept the general terms and conditions of sample acceptance and confirm the accuracy of the information I have declared. The damages of the negative situations that may arise from the incorrect information belong to us. I declare that we accept to perform the tests requested in the form and to pay the amount to be invoiced to us based on the prices in the offer given for this work. |
| **Test Requester****( Name Surname** **/** **Stamp / Signature / Date)** | **Sample Receiver****( Name Surname** / **Signature / Date)** | **Sample Acceptor****( Name Surname / Signature / Date)** |
|  |  |  |