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| **Questionnaire for Medical Device Classification Determination** | | | |
| NO. : MD-RC-KR-15201 | | | |
| Company or Organization | |  | |
| Company Address (or website) | |  | |
| Contact information (name, Email, Phone etc.) | |  | |
| Product name | |  | |
| **Delivery Schedule** | | | |
| Please prepare the required data/document/sample or other material upon the request and send it to CIRS before the start of each process | | | |
| **General Information for Classification Determination** | | | |
| **Items** | | **Description** | |
| Product Common Name In Chinese(optional) | |  | |
| Product English Name | |  | |
| Has It Been Submitted for Registration Assessment？ | | □ Yes □ No | |
| Is It The First Time to Apply for Product Classification? | | □ Yes □ No | |
| The Origin Country Product Type | | □ Active Product □ Passive Product □ IVD | |
| Intended Use (include the applicable scope, contraindications, etc.) | |  | |
| Structural Characteristics | |  | |
| Operation Principle or Mechanism | |  | |
| Intended for Use, Use Status, Use Part, Use Term and Use Method | |  | |
| Material Characteristics | | List The Compositions and Characteristics. | |
| If It Belongs to IVD Products, Submit Information of Main Raw Materials, Production Technology, Reaction System, etc. | |  | |
| Critical Risk of The Product | |  | |
| Domestic or Abroad Similar Product | | Please Provide The Name, Manufacturer, Registration Certificate Number or Other Supporting Documents of The Similar Product. | |
| Applicant's Opinion | | □I，□II，□III，□Non-Medical Device，□Depends on The Specific Circumstances | |
| Other Content to Be Explained | |  | |
| The Basis of The Applicant's Opinion | |  | |
| Needed Attachments | | Manual Instruction (Both in Original Language and Chinese Are Required) | |
| Photos and/or Structural Diagram of The Product | |
| Product Standard and Explanation of Compilation | |
| Documents Proving That Your Product Has Been Approved or Recognized to Be sold as Medical Device (Registration Certificate Both in Original Language and Chinese) | |
| Other Attachment | |