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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 |