# **NEXTGEN MD FORM**

*Please note that the premarket registration submission requirements per GN-15 still applies. You can include the information from Part 1 and 2 of this form as an appendix to this form.* ***If the information provided within this form is incomplete, the application will be reviewed as per the standard FULL evaluation route.***

Qualifying criteria

|  |  |
| --- | --- |
| **General Medical Devices** | **In-Vitro Diagnostic Medical Devices** |
| All models in the application must meet ALL of the following criteria when compared with the registered device:   1. Same product type 2. Identical validation for Biocompatibility, Sterilization AND Shelf-life | All reagents in the application must share ALL of the following criteria when compared with the registered device:   1. Identical formulation AND labelled storage condition 2. Identical intended use and indications for use 3. Identical sample type |

# **PART 1 COMPARISON TABLE OF NEXT GENERATION DEVICE AND REGISTERED DEVICE**

|  |  |  |
| --- | --- | --- |
|  | **Next generation device** | **Registered device** |
| Device listing number(s) |  |  |
| Job reference number(s) |  |  |
| E.g. Intended use | A comprehensive comparison of the next generation device with the registered device, including but not limited to the intended use/indications for use, design characteristics, mode of action/principles of operation, material/formulation, technical and performance specifications, packaging configuration, manufacturing process, sterilization method and process, compatible accessories/calibrators/controls/analyzers. This may be accompanied by pictures/diagrams with supporting text to highlight the differences. |  |
| Indications |  |  |
| Principles of operation |  |  |
| Material |  |  |
| Packaging |  |  |
|  |  |  |
|  |  |  |

# **PART 2 JUSTIFICATION ON RELEVANCE OF PREVIOUSLY SUBMITTED DATA TO THE NEXT GENERATION DEVICE**

Please note that only identical test reports (same report version) can be leveraged. Please include only relevant design verification and validation aspects that you wish to leverage in this section.

|  |  |  |
| --- | --- | --- |
| **Design verification and validation** | **Filename of report(s)** | **Justification** |
| E.g. Biocompatibility | List the exact filename of the report submitted in the application of the registered device(s). This same document with the same filename is to be submitted in the premarket application of the next generation device. | A detailed critical analysis on why the next generation device may leverage on the data of the registered device(s). If multiple registered devices and/or device listings are to be leveraged on, please specify the device name and the associated device listing in the table to facilitate review. |
| Sterilization |  |  |
| Shelf-life |  |  |
| Analytical Sensitivity |  |  |
| Analytical Specificity |  |  |