1. **COMPANY INFORMATION**

|  |  |
| --- | --- |
| **Company Name** |  |
| **Company Address** |  |
| **SRN** |  |
| **Contact Person** |  |
| **Contact Information** |  |

|  |
| --- |
| Where the change includes, new, not approved products (scope extension), new locations, new critical supplier, please fill in FR.MED.01 Application form and its related annexes for the change notification. The manufacturer shall not make any significant changes according to MDCG 2020-3 rev.1 for the legacy devices during the transition period defined in (EU) 2023/607 Regulation. |

1. **DEFINITION OF CHANGE**

|  |  |
| --- | --- |
| **Definition of Change**  (please give a summary of change) |  |
| **Certificate numbers effected by the change** |  |
| **Products/Models related to the change request** |  |

**Please select from below. If the changes are related with both product and system, please select from both.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Changes Related with Product** | | **Changes Related with System** | |
| Product/Product Line Addition |  | Company Acquisitions |  |
| Additional Models |  | Changes in the Legal Fom  Changes in the type of legal form (legal entity remains) (e.g., limited company, holding) |  |
| Change of Approved Model Definition, Device Identifiers |  | Company Name Change |  |
| Change of Approved Intended Use  (e.g., Indications, Contra-Indications, Adverse Effects, Warnings) |  | Relocation |  |
| Change in Approved Design  (e.g., Specifications, used materials, components, substances, packaging, safety related functions, changes in substances) |  | Address Definition Change (same location continues) |  |
| Change of Approved Performance  (e.g., shelf life) |  | Additional Location for partly/fully Regulatory, Quality, Purchasing Control, Manufacturing, Design, Service, Storage, Release, PMS/PMCF |  |
| Additional Accessories |  | Additional Other Location Types |  |
| Others  Please Define the Change: |  | Additional Relevant Critical Supplier/Subcontractor |  |
| Replacement of a current Critical Supplier/Subcontractor |  |
| Staff Changes  -Critical Staff changes (managerial, design, manufacturing, quality, regulatory, service, release, PMCF)  -Person Responsible for Regulatory Compliance change |  |
| Changes in quality management system structure |  |
| Changes in procedures effecting MDR compliance |  |
| New manufacturing Lines |  |
| Changes effecting validated processes  - New manufacturing/testing lines  - New manufacturing/testing machines or accessories  - Replacement of manufacturing/testing machines or accessories  - New or upgraded technology  - Changes in validated sterilization parameters and equipment  - Changes in validated process software  - Implementing new process software  - Changes in packaging process parameters and equipment |  |
| Changes in controlled environments |  |
| Changing the EU Authorized Representative |  |
| Other  Please Define the Change: |  |

|  |  |
| --- | --- |
| **Plan Related with Change / Comparison of New-Previous Situation** |  |
| **Documents Effected by The Change**  (Please state the section and page information and please send the changed documents.) |  |
| **New Documents Created as A Result of The Change** (e.g., Test Report)  (Please send related documents.) |  |
| **Reason for The Change** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Company Representative For Change Notification** | **Name, Surname** | **Signature** | **Date** |
|  |  |  |