1. **COMPANY INFORMATION**

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| --- | --- |
| **Company Title** |       |
| **Company Address** |       |
| **Contact Person** |       |
| **Contact Information** |       |

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| When applicable please additionally use FR.MED.01 Application Form and its related annexes. |

1. **DEFINITION OF CHANGE**

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| --- | --- |
| **Definition Of Change**(Please give a summary of change)  |       |
| **Certificate numbers effected by the change** |       |

**Please select from below. If the changes are related with both product and system, please select from both. For more information regarding change notification please see MDCG 2020-3 guidance document.**

|  |  |
| --- | --- |
| **Changes Related with Product** | **Changes Related With System** |
| Product/Product Line Addition | [ ]  | New Company or New Company Name | [ ]  |
| Additional Models | [ ]  | Address Change | [ ]  |
| Change of Model Definition | [ ]  | Additional Location | [ ]  |
| Change of Intended Use(e.g., Indications, Contra-Indications, Adverse Effects, Warnings)  | [ ]  | Additional Critical Supplier | [ ]  |
| Change In Approved Design(e.g. Specifications, used materials, components, packaging, safety related functions  | [ ]  | Quality Management System Changes(e.g., Critical organizational changes, structural changes in the quality management system  | [ ]  |
| Change Of Performance(e.g. shelf life)  | [ ]  | Change of European Representative | [ ]  |
| Additional Accessories | [ ]  | Changes In Production and Quality Control Processes (e.g., new technology) | [ ]  |
| Others | [ ]  | Changes in Special Processes(e.g., Sterilization, Packaging, Software) | [ ]  |
| Please Define:       | Other | [ ]  |
| Please Define:       |

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| --- | --- |
| **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 these documents)  |       |
| **Reason For the Change** |       |

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| **Company Authorized for Change Notification**  | **Name, Surname** | **Signature** | **Date** |
|       |  |       |