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: | |

|  |  |
| --- | --- |
| **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** |
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