

### A) COMPANY INFORMATION

Company Title	
Company Address	
Contact Person	
Contact Information	

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

### B) DEFINITION OF CHANGE

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

Company Authorized for Change Notification	Name, Surname	Signature	Date