

## Change Notification Form

### A) COMPANY INFORMATION

<b>Company Name</b>	
<b>Company Address</b>	
<b>SRN</b>	
<b>Contact Person</b>	
<b>Contact Information</b>	

Where the change includes new, not approved products (scope extension), please fill in FR.MED.01 Application form and its related annexes for the change notification.

### B) DEFINITION OF CHANGE

<b>Definition of Change</b> (please give a summary of change)	
<b>Certificate numbers effected by the change</b>	

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	<input type="checkbox"/>	New Company or New Company Name Changes in the type of legal form (legal entity remains) (e.g., limited company, holding)	<input type="checkbox"/>
Additional Models	<input type="checkbox"/>	Address Change (location changes) Address definition changes (same location continues)	<input type="checkbox"/>
Change of Approved Model Definition	<input type="checkbox"/>	Additional Location	<input type="checkbox"/>
Change of Approved Intended Use (e.g., Indications, Contra-Indications, Adverse Effects, Warnings)	<input type="checkbox"/>	Additional Relevant Critical Supplier/Subcontractor	<input type="checkbox"/>
Change in Approved Design (e.g., Specifications, used materials, components, substances, 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 Approved Performance (e.g., shelf life)	<input type="checkbox"/>	Changing the EU 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 the Change:		Other	<input type="checkbox"/>
		Please Define the Change:	

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

Company Representative For Change Notification	Name, Surname	Signature	Date