

TITLE: Regulatory Compliance Impact Assessment - Template

REV.: C

| REGULATORY COMPLIANCE IMPACT ASSESSMENT | | | | |
|---|-------------------------------------|--|---|--------------------------|
| <input type="checkbox"/> EPD <input type="checkbox"/> ECR <input type="checkbox"/> GEPC <input type="checkbox"/> <Insert Other> | | Number: <Insert # associated with change.> Level: L2L | CAPA Associated: <Select one.> CAPA ID: <Insert CAPA ID> | |
| Problem Statement / Change Scope | | | | |
| <Identify the problem statement or the engineering design change scope that is to be assessed and why the change is being made.> | | | | |
| Description of the Product | | | | |
| <Insert a brief description of the product and accessories in scope of this change.> | | | | |
| Affected Product Family / Model(s) and Accessories (Do not embed documents for PDF visibility) | | | | |
| Models: <Identify the SKUs impacted by this design change.> Accessories: <Identify any accessories impacted by this design change. If no accessories are impacted, state "N/A – No accessories are identified as being impacted".> Note: Complete SKUs/Models shall be provided, with descriptions (if needed). If the product has SKUs that fall under multiple "device types", identify the device type for the SKUs (i.e., table provided that shows the SKUs and which device types they fall under). If the Accessories are used with both GP and non-GP models, this must be specified. | | | | |
| GENERAL | | | | |
| Impact to Manufacturer | | | | |
| Design Owner: <Choose an item.> Other (if applicable): <Fill in if "Other" is chosen.> Name of OEM (if applicable): <Name of OEM> Manufacturing Site: <input type="checkbox"/> AVL <input type="checkbox"/> MAR <input type="checkbox"/> LSB <input type="checkbox"/> OHA <input type="checkbox"/> SNG <input type="checkbox"/> Other <input type="checkbox"/> OEM <input type="checkbox"/> CM (External) Other (if applicable): <Fill in if "Other" is chosen.> Name of OEM (if applicable): <Name of OEM> CM (External – if applicable): <Name of CM> Design is Copy Exact: <Choose an item.> | | | | |
| New models SKUs to be created in scope of this project: <If there are no new SKUs to be created, place N/A in this field.> | | | | |
| Device Type (based on Intended Use) and Known Markets | | | | |
| Select the appropriate Device Type category based on the Intended Use for the product (reference the products User Manual). If the product family and/or accessory(s) span between multiple device types, all Device Types must be selected. | | | | |
| Device Type | N. America | EMEA | LATAM | APAC |
| General Purpose (GP) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Medical (MD) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| In Vitro Diagnostics (IVD) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Gen Purpose + Cell Gene Therapy (GP + CGT) | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Accessories in Scope (GP / MD / IVD / GP + CGT) <Highlight only impacted device type> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |