TITLE: Regulatory Compliance Impact Assessment - Template
REV.: C

REGULATORY COMPLIANCE IMPACT ASSESSMENT

☐EPD ☐ECR ☐GEPC ☐ *<Insert Other>*	**Number:** *<Insert # associated with change.>* **Level:** L1	**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: ☐AVL ☐ MAR ☐ LSB ☐ OHA ☐ SNG ☐ Other ☐OEM ☐ 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)	☑	☑	☐	☐
Medical (MD)	☑	☑	☐	☐
In Vitro Diagnostics (IVD)	☑	☑	☐	☐
Gen Purpose + Cell Gene Therapy (GP + CGT)	☑	☑	☐	☐
Accessories in Scope (*GP / MD / IVD / GP + CGT*) *<Highlight only impacted device type>*	☑	☑	☐	☐