ThermoFisher SCIENTIFIC

FENG093

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

Template Instructions: Delete "Template Instructions" Section when using template.

- Complete **ALL** sections of the template.
- This form is to be used for L1, L2L, L2, and L3L projects.
- The Medical assessment is only required for medical, gene therapy, or IVD products and accessories.
- After completing the Scope Assessment, indicate required project actions, adding where needed. After completing all sections, sign as indicated in the approvals section. This form is not all encompassing for all country specific requirements, any other country specifications found can be provided within the project plan. "*" where used indicates voluntary requirements.
- Keep content in black.
- Informational notes are in *<blue italics>* where content can be added or deleted**.** If content is added ensure it is black font without italics in the completed Regulatory Compliance Impact Assessment.
- The Plan summarized in this template will be updated based on the requirements outlined in SOP0018571: CTT Business Unit Engineering Change Control Process (ENG016).
- Do not include *<informational notes>* in the completed Regulatory Compliance Impact Assessment. Replace the *<informational notes>* with the required information as guided by the informational notes.
- If a section is not applicable (N/A) the output document shall explain why the section is N/A. Do not simply delete sections without a rationale.
- Please delete the template revision history the output document. The Appendixes may be kept if it is needed.
- The output document of this Regulatory Compliance Impact Assessment shall be uploaded into Arena under the design change that is being reviewed (i.e., "Files" tab).

Important:

- Any documents (i.e., engineering assessments, other regulatory assessments) that are to support this document shall be appended to the word file or PDF prior to the document receiving signatures. Documents shall not be embedded within the word file.

Template Revision History:

Rev.	*Effective Date*	*Section*	*Description*
A	04-08-2012	All	Initial Release.
B	06-30-2021	All	Added MDD requirements; Updated the document to reference revision B.
C	1-19-2024	All	Rewrite of entire document to be focused on the “impact” of the design change to the product’s compliance.

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REGULATORY COMPLIANCE IMPACT ASSESSMENT

☐EPD ☐ECR ☐GEPC ☐ *<Insert Other>*	**Number:** *<Insert # associated with change.>* **Level:** L1	**CAPA Associated:** Yes **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: ASH **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: Yes - Scope of models are Copy Exact. Customer Approval Required

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>*	☐	☐	☐	☐

RISK MANAGEMENT FILE IMPACT *(All products)*	
☐ The change does not impact the Risk Management File **Justification:** *<A justification as to why this section is not in scope must be provided. Reference to relevant documentation should be provided.>*	
Scope Assessment	*Mark where applicable* ☐ The product family does not have a Risk Management File or does not have a Risk Management File aligned to the latest revisions in the QMS. ☐ The change introduces new usage conditions, or risk of harm as defined in the Risk Management Procedure (*Patient, Samples, Operators, Environment, etc.*). ☐ The change affects the current risk probability or severity associated with existing hazards ☐ The change will mean that the device will have different end users or be used in a different manner ☐ The performance evaluation data for the original device is not sufficient to confirm conformity of the changed device with the required characteristics and performance ☐ The change involves the manufacturing process (i.e., technologies, product lines) ☐ The change impacts End of Line (EOL) testing procedures (e.g., TP902 – Test procedure for all Hi Pot and Hypatia Equipment Test Machines) ☐ The change requires a process validation ☐ The change affects agreements and/or arrangements (e.g., verification, validation, organizational structure, production site, outsourcing, subcontracting) for ensuring continued compliance with the requirements ☐ The change results from actions taken related to concerns arising from post-market surveillance including incidents/recalls/complaints (CAPA associated) ☐ The change impacts Quality Control procedures, incoming acceptance criteria, or involves a change in supplier ☐ (Medical) The change results from characteristics not previously considered in the clinical evaluation ☐ (Medical) The change is driven by the development of the state of the art (e.g., latest technology) ☐ Other: *<If "Other" is selected, provide more information here>*
Project Actions	**Next Steps:** Review and where necessary revise the Risk Management File **GEPC# (if applicable)**: *<Insert GEPC number if a new project is being created>* **Other (if applicable)**: *<If "Other" is selected, provide more information here>*
	Notifications to: ☐ CAPA owner notified

PRODUCT SPECIFIC COMPLIANCE ASSESSMENT *(All products)*	
☐ The change does not impact the performance compliance of the product. **Justification:** *<A justification as to why this section is not in scope must be provided. Reference to relevant documentation should be provided.>*	
Scope Assessment	*Mark where applicable* ***Clean Room Impact Determination:** ☐ Changes affect degradable, moving or friction generating components (air filters, fans, hinges, etc.) ☐ Changes affect the airflow into, throughout, and out of the unit (airflow vent, rearranging components, deck size, etc.) ☐ Product currently has outdated testing or missing testing to the latest requirements. Requested to add in scope of the current project. ***Energy Star Impact Determination (Refrigerators/Freezers/ULT only):** ☐ Changes affect critical components in compliance files (Electrical, refrigeration, labels) ☐ Changes affect the product performance, peak variation, temperature stability, door open recovery times ☐ Changes will be made to the product power specifications, refrigeration system, or electrical systems ☐ Changes to the internal cabinet size, construction, or configuration (inner doors, shelving, port holes) ☐ Change to defrosts, setpoint ranges, or code versions ☐ Changes to the software affecting behavior or timing of behaviors ☐ Product currently has outdated testing or missing testing to the latest requirements. Requested to add in scope of the current project. **ErP Impact Determination (Chillers: Low Temperature / Medium Temperature / Height Temperature)** ☐ Changes affect the cooling capacity to cool down and maintain the temperature of the liquid ☐ Changes affect the functionality of the medium (refrigerant, water, etc.) to chill the system continuously ☐ Changes may affect the power input specifications ☐ Product currently has outdated testing or missing testing to the latest requirements. Requested to add in scope of the current project. ***NSF456 Vaccine Impact Determination (Ref/Frz only):** ☐ Changes affect critical components in compliance files ☐ Product currently has outdated testing or missing testing to the latest requirements. Requested to add in scope of the current project.

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NSF49 BSC Impact Determination (BSC only):

- ☐ Changes affect critical components in compliance files
- ☐ Changes to the materials of construction or coatings (paint)
- ☐ Changes impact air flow (blowers, power supp, filters, paper catch areas, filter screen)
- ☐ Changes to the software
- ☐ Changes impacting stability (change weight distribution or change to stands)
- ☐ Changes impact cleanability (Sealing of openings that could harbor contamination, fasteners - Philip screws not allowed)
- ☐ Changes impact the cabinet pressure decay test (seals, cabinet materials)
- ☐ Changes impact labels or markings (add, remove, location change)
- ☐ Product currently has outdated testing or missing testing to the latest requirements. Requested to add in scope of the current project.

Project Actions — Impacted or Created

	N. America	LATAM	EMEA	APAC
Agency Test Reports	☐ ENERGY STAR* ☐ NSF49 BSC* ☐ NSF456 Vaccine*	☐ Clean Room Particulate 14644-14*	☐ Clean Room Particulate 14644-14* ☐ ErP Directive *(Chillers only)*	☐ Clean Room Particulate 14644-14* ☐ South Korean Act on Environmental testing and Inspection
	☐ Other (if applicable): *<Select "Other" if the report is not listed above. Provide more information here.>* Country: *<Specify the Country where this requirement is present>*			
Marks & Labels	☐ ENERGY STAR* ☐ CE (Self-Declared) ☐ Other (if applicable): *<If "Other" is selected, provide more information here.>*			
Documents	☐ Marketing claims ☐ CE DoC (Self-Declared) ☐ Other (if applicable): *<If "Other" is selected, provide more information here.>*			

Next Steps:

Testing Required: External Testing

Other (if applicable): *<If "Other" is selected, provide more information here.>*

Impacted Documents:

☐ Agency Report Revision ☐ Revise Engineering Drawings/Documents ☐ Revise Regulatory Documents (Cloud Drive)