ThermoFisher SCIENTIFIC

FENG093

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

REGULATORY COMPLIANCE IMPACT ASSESSMENT

☒ **EPD** ☐ **ECR** ☐ **GEPC** ☐ *<Insert Other>*	**Number:** EPD-004881 **Level:** L2L	**CAPA Associated:** No **CAPA ID:** N/A

Problem Statement / Change Scope

Problem: Current part, Hubbel GFRST15W is discontinued
Requested Action: Replace part with the Hubbel GRF15W. Need to qualify new part for LRF.

Description of the Product

GFCI is used in chromatography assembly placed inside TSX & TSG units

Affected Product Family / Model(s) and Accessories (Do not embed documents for PDF visibility)

Models: -
TSX-LRF & TSG (Chromatography) A-voltage and D-voltage refrigerators (05) only

TSX2305CA	TSX3005CA	TSX4505CA	TSX5005CA
TSX2305CD	TSX3005CD	TSX4505CD	TSX5005CD
TSX2305CY	TSX3005CV	TSX4505CY	TSX5005CY
TSX2305CZ	TSX3005CY	TSX4505CZ	TSX5005CZ
CH2305CA	CH3005CA	CH4505CA	CH5005CA
TSG2305CA	TSG3005CA	TSG4505CA	TSG5005CA

Accessories: N/A

Refer attached where used.

GENERAL

Impact to Manufacturer

Design Owner: ASH **Other (if applicable): NA** **Name of OEM (if applicable):** *N/A*

Manufacturing Site: ☒ AVL ☐ MAR ☐ LSB ☐ OHA ☐ SNG ☐ Other ☐ OEM ☐ CM (External)

Other (if applicable): **Name of OEM (if applicable):**

CM (External – if applicable):

Design is Copy Exact: N/A

New models SKUs to be created in scope of this project:

N/A

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:** This is a drop-in replacement for GFCI, The RMF for TSX series 329376I01-03 is not impacted with the said change.	
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:** *<Choose the project action item that would need to be completed based on the scope assessment.>* **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:** This change does not affect product specific compliance since the project scope drop-in replacement for GFCI part.	
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: No test captured - Rationale provided in plan
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)
☐ Marketing claims are validated ☐ Marketing claims have not been validation
☐ Change impacts product, scope is defined as requiring a new project.
GEPC# *<Insert GEPC number if new project is being created>*
☐ Other (if applicable): *<If "Other" is selected, provide more information here.>*

Notifications to:

☐ CB of changes (ENERGY STAR, required if not testing) ☐ Energy Star Team Leads (ENERGY STAR)
☐ RA at Implementation Manufacturing Location ☐ South Korean RA Team for in-country Testing
☐ Authorities of Product Changes where registered ☐ Other (if applicable): *<If "Other" is selected, provide more information here.>*

DESIGN SAFETY, EMC, & WIRELESS COMPLIANCE ASSESSMENT *(All products)*

☒ The change does not impact the design safety, EMC, and/or wireless compliance. Like for like components (i.e., PCBA components) should still be evaluated to ensure the safety report has not been impacted.
Justification: For TFS PN# 49171H03, MFR PN# GFRST15W No safety file update required for UL file no. E473332-D1017, SA5215 sec.27.

Scope Assessment

Mark where applicable

☐ Does the change affect specs, listings, warnings, or text on critical components in compliance files?
☐ Are the specs/ratings of the end product going to be changed? (power = re-evaluate markets)
☐ Are the specs/ratings of the product's environment going to be changed? (Env. conditions, spacings, etc.)
☐ Are the product features / use being impacted?
☐ Are materials going to be changed (Keeping the same part number or not)?
☐ Are labels, IFU, or customer facing information going to be changed?
☐ Will the manufacturing location or applicant of the file need to change?
☐ (Supplier change) Does the change impact split inspection locations and files? (*Common for PCBA or enclosed subassemblies*)
☐ Product currently has outdated testing or missing testing to the latest accepted requirements. Requested to add in scope of the current project.
☐ Other (if applicable): *<If "Other" is selected, provide more information here.>*

Project Actions — Impacted or Created

Agency Test Reports

Safety Reports Impacted:
☐ NRTL Listing, Report # *<Insert Report Number>*
☐ CB Safety, Report # *<Insert Report Number>*
☐ Informative Safety, Report # *<Insert Report Number>*

EMC Reports Impacted:
☐ EMC (EN report), Report # *<Insert Report Number>*
☐ FCC, Report # *<Insert Report Number>*
☐ ICES, Report # *<Insert Report Number>*
☐ Wireless, Report # *<Insert Report Number>*

☐ Other: *<If "Other" is selected, provide more information here.>*, Report # *<Insert Report Number>*

Marks & Labels
Note: These markings may not be all inclusive. If another marking is used, this

N. America		LATAM	EMEA	APAC
☐ UL	☐ CSA	☐ IRAM-S	☐ CE DoC (Self-Declared)	☐ KC Mark
☐ ETL	☐ TUV	☐ INMETRO	☐ CE DoC (EU NB)	☐ EAC
		☐ ANATEL		

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	shall be place in the "Other" category.	☐ FCC / ICES ☐ NSF ☐ NOM	☐ S Mark	☐ UKCA ☐ LNE ☐ GS ☐ WEEE	
		☐ Other: *<Select "Other" if the mark/label is not listed above. Provide more information here.>* Country: *<Specify the Country where this requirement is present>*			
	Documents *Indicates voluntary requirements	☐ FCC Declaration	*No documents currently identified within this region.*	☐ CE DoC (Self-Declared) ☐ CE DoC (EU NB) ☐ UKCA Declaration	*No documents currently identified within this region.*
		☐ Other: *<Select "Other" if the document is not listed above. Provide more information here.>* Country: *<Specify the Country where this requirement is present>*			

Next Steps:

Testing Required: No test captured - Rationale provided in plan
Other (if applicable): *<If "Other" is selected, provide more information here.>*

Impacted Documents:

☐ No Update Required (justification within plan required) ☐ Paperwork update only
☐ Registration with Agency required (FCC, etc.) ☐ Revise Engineering Drawings/Documents (i.e., labels)
☐ Revise Regulatory Documents (i.e., declarations) ☐ Re-evaluate **market** requirements due to changes.
☐ Re-evaluate **product** requirements due to changes. ☐ Re-evaluate **process** requirements due to changes.
☐ Other: *<If "Other" is selected, provide more information here.>*

Notifications to:

☐ Regional Leads if registered (i.e., Saudi SASO, KC Mark, Australian RCM) ☐ RA at Implementation Manufacturing Location
☐ Authorities of Product Changes where registered ☐ Other: *<If "Other" is selected, provide more information here.>*

END PRODUCT ENVIRONMENTAL ASSESSMENT *(All products)*

☐ The change does not impact the end product environmental compliance. (i.e., change is associated with documentation updates)
Justification: There is no TFS part number change. Environmental declaration (REACH, ROHS and Prop 65) for proposed part GFR15W is to be provided.

Scope Assessment

Documents to reference for what is needed to meet environmental compliance:
CS Drawing# 260111S01 *TC Drawing # 015955* *MAR Drawing# GT260111*

Mark where applicable

☐ Change adds new or removes any components from the product (BOM update)
☐ The supplier of a part number is changing
☐ The manufacturing or internal part number is changing
☐ End product impacted currently has an outdated BOM in Greensoft or BOM is not uploaded into GreenSoft. Requested to add in scope of the current project.
☐ Other: *<If "Other" is selected, provide more information here.>*

Internal Forms or Agency Test Reports	☒ GreenSoft Item Submission ☐ GreenSoft BOM Upload Form ☒ GreenSoft Customer Collected Documents Form			
	☐ Other: *<If "Other" is selected, provide more information here.>*			
Marks & Labels Note: These markings may not be all inclusive. If another marking is used, this shall be placed in the "Other" category.	**N. America**	**LATAM**	**EMEA**	**APAC**
	☐ Prop65 ☐ FIFRA Pesticide (UV Lamp)	☐ WEEE	☐ WEEE ☐ F-Gas ☐ PFAS	☐ WEEE ☐ China RoHS (C-RoHS)
	☐ Other: *<Select "Other" if the mark/label is not listed above. Provide more information here.>* Country: *<Specify the Country where this requirement is present>*			
Documents Note: If another document is needs to be created or update, this shall be placed in the "Other" category.	☒ Prop65 Declaration ☐ FIFRA Pesticide Product Reporting (UV Lamp)	☐ Montreal Protocol Declaration	☒ REACH Declaration ☒ RoHS Declaration ☐ F-Gas Declaration ☐ CE Declaration (Self-Declared)	☐ C-RoHS "Tic-Tac Table" Declaration
	☐ Other: *<Select "Other" if the document is not listed above. Provide more information here, ex. Coneg, PFAS.>* Country: *<Specify the Country where this requirement is present>*			

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Project Actions

Next Steps:

Testing Required: No test captured - Rationale provided in plan

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

Impacted Documents:

☐ No Update Required ☒ Upload GreenSoft Form(s) ☐ Revise Engineering Drawings/Documents (labels)

☐ Revise Regulatory Documents (i.e., declarations)

☐ Change impacts product, scope is defined as requiring a new project.

GEPC# *<Insert GEPC number if new project is being created>*

☐ Other: *<If "Other" is selected, provide more information here.>*

Notifications to:

☐ EPA Lead if registered (FIFRA) ☐ GreenSoft User to load GreenSoft BOM changes (i.e., component or supplier change – site: GS Submission)

☐ Other: *<If "Other" is selected, provide more information here.>*

MEDICAL ASSESSMENT *(Not applicable for General Purpose Products)*

PART A SAFETY, COMPATIBILITY, EFFECTIVENESS

(Mark if yes and complete Scope Assessment below)

☐ Will the change affect the safety, compatibility, or effectiveness of the device?

☐ Will the technology, engineering design, or performance of the device or packaging change?

☐ Is the change introducing a new material, or alternate component, or is it a supplier change?

Scope Assessment

☐ Does the change include or impact the product's Intended use?

☐ Does the change introduce new risks of harm to humans, property, or the environment?

☐ Will the change affect the standards this product relies upon?

☐ Is there another registration classification that this product will align to? *<Provide more information here.>*

PART B LABEL IMPACTS

(Mark if yes and complete Scope Assessment below)

☒ Will the change affect product, packaging, electronic literature, or labelling?

Scope Assessment

Changes to Documents

☒ IFU/User Manual ☐ Service Manual ☐ Translation(s) ☐ Technical Data Sheets

☐ ESI/Quick Start Guide ☐ Marketing Material ☐ Other: *<If "Other" is selected, provide more information here.>*

Changes to Packaging/Shipping

☐ Change in label material ☐ Marking(s) ☐ Indication of Use ☐ e-IFU section

☐ Other: *<If "Other" is selected, provide more information here.>*

Changes to Product/Product Label

☐ Intended Use ☐ Translation(s) ☐ Change in specs/ratings ☐ Change in the warnings/precautions

☐ Other: *<If "Other" is selected, provide more information here.>*

PART C TECHNOLOGY, ENGINEERING, AND PERFORMANCE CHANGE

(Mark if yes and complete Scope Assessment)

☒ Will the technology, engineering design, performance of the device, or packaging change?

Scope Assessment

☐ Change in control mechanism, operating principle or energy type?

☐ Does the change impact the Product Requirements?

☐ Does the change impact a component that is subjected to sterilization, cleaning, or disinfection?

☐ Does the change to the part require that sterilization validation, cleaning validation, or disinfection validation should be repeated?

☒ Does the change affect the performance or accuracy of the device?

☐ Does the change involve a component, software/firmware item or other part responsible for the product achieving its intended use?

☐ Change in packaging design?

☐ Change uses the same technology and classification as described in a previously cleared 510(k) or 510(k) exempt version?

☐ Does the change impact safety critical (i.e., 61010, EMC), critical to quality, critical to performance components? *(See ENG016, CTT Business Unit Engineering Change Control Process procedure for definitions.)*

☐ Does the change affect the intended use of the device?

☐ Risk-based assessment of the changed device identify any new risks or significantly modified existing risks?

☐ Is clinical data necessary to evaluate the safety or effectiveness for purposes of design validation?

PART D MATERIAL / SUPPLIER CHANGE

(Mark if yes and complete Scope Assessment below)

☐ Is the change introducing a new material, alternate component, or is it a supplier change?

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Scope Assessment

☐ Is this a change in material type, material formulation, chemical composition, or the material's processing?
☐ Will the changed material directly or indirectly contact body tissues or fluids *(Including operators and service)?*
☐ Does a risk assessment identify any new or increased biocompatibility concerns?
☐ Has the manufacturer used the same material in a similar legally marketed device?
☐ Could the change affect the device's performance specifications?
☐ Does the supplier change impact split inspection locations and files? *(Common for PCBA or enclosed subassemblies)*
☐ Does the supplier change affect critical components in compliance files?

Part E SOFTWARE/FIRMWARE CHANGES

(Mark if yes and complete Scope Assessment below)
☐ Is there a change to product software or firmware?

Scope Assessment

☐ Does the SW Change impact the SW documentation? (as applicable SW QAPs/SOPs for AVL / MAR sites)
☐ Does the SW Change include a security patch related to a known vulnerability?
☐ Is the SW Change made solely to return the system into specification of the most recently cleared device?
☐ Does the SW change introduce a new risk or modify an existing risk?
☐ Does the change create or necessitate a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm?
☐ Could the change impact functionality or performance specifications that are directly associated with the intended use or safety the device?
☐ Are there additional software factors that may affect the decision to file? (e.g., Infrastructure, Architecture, Core algorithm, Re-engineering and refactoring etc.)
Refer to SW Substantial change Determination

Project Actions

Impacted or Created

Approvals & Registrations
Note: These markings may not be all inclusive. If another marking is used, this shall be place in the "Other" category.

N. America	LATAM	EMEA	APAC
☐ USA: FDA 510(K) Exempt ☐ USA: FDA 510(K) ☐ Canada: MDSAP ☐ Mexico: COFEPRIS	☐ Argentina: ANMAT ☐ Brazil: ANVISA ☐ Brazil: INMETRO ☐ Columbia: INVIMA ☐ Costa Rica: MoH ☐ Ecuador: ARCSA ☐ El Salvador: DNM ☐ Guatemala: MSPAS ☐ Nicaragua: MINSA ☐ Panama: MINSA / MoH ☐ Peru: MINSA	☐ EU: CE (NB) ☐ UK: MHRA ☐ UK: UKCA (NB) ☐ UK: UKCA ☐ Iceland: IMA ☐ Israel: MoH ☐ Egypt: EDA ☐ Saudi Arabia: SFDA ☐ Turkey: TITCK ☐ Norway: NoMA ☐ Serbia: ALIMS ☐ Ukraine: SMDC ☐ Morocco: DMP	☐ China: NMPA ☐ Malaysia: MDA ☐ South Korea: MFDS ☐ Taiwan: TFDA ☐ India: CDSCO ☐ Singapore: HSA ☐ Japan: PMDA ☐ Australia: TGA ☐ Hong Kong: MCO ☐ Indonesia: MoH ☐ New Zealand: MEDSAFE

☐ Other: *<Select "Other" if the approval/registration is not listed above. Provide more information here.>*
Country: *<Specify the Country where this requirement is present>*

Agency Test Reports

☐ IEC 60601 Report(s), Report # *<Insert Report Number>*
☐ ILAC/IAAC Report, Report # *<Insert Report Number>*
☐ IEC 61010 Report(s), Report # *<Insert Report Number>*
☐ CB Scheme Report, Report # *<Insert Report Number>*
☐Other: *<Select "Other" if the report is not listed above. Provide more information here>*, Report # *<Insert Report Number>*

Marks & Labels

☐ UDI ☐ CE (EU NB) ☐ Packaging/Shipping Labels ☐ Product Label
☐ Other: *<If "Other" is selected, provide more information here.>*

Next Steps:

Testing Required: In-house Testing
Other (if applicable): *<If "Other" is selected, provide more information here.>*
Registration Impact: *<Choose an item.>*
Other (if applicable): *<If "Other" is selected, provide more information here.>*

☐ Verify Intended Use consistency ☐ Verify changes documented in TF / DHF ☐ Verify changes are documented in DMR
☐ Submit to EU NB ☐ Submit and Update TF / DHF ☐ Verify 510k for change impact
☐ Other: *<If "Other" is selected, provide more information here.>*

Notifications to:

☒ Regional RA Lead(s) ☐ FDA Correspondent(s) ☐ EU PRR(s) ☒ Notify RA at Implementation Manufacturing Location
☐ Notify Authorities of Product Changes where registered ☐ Other: *<If "Other" is selected, provide more information here.>*

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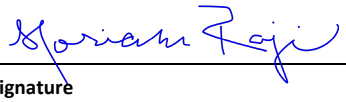
Note: If more than one product type is identified, please ensure all responsible RA individuals have signed this document. Copy only the signature blocks as needed.

PROJECT PLAN ASSESSMENT (Completed during project phases)	
• This is a drop-in replacement the proposed part (GFR15W) has similar or better specs than the current part (GFRST15W). • For TFS PN# 49171H03, MFR PN# GFRST15W No safety file update required for UL file no. E473332-D1017, SA5215 sec.27. No EMI/EMC report update needed as well. • FAI and Functional testing to be performed as per V-000150. • Manual update is required, EPD for Manual update to capture GFCI details with new picture will be created after testing is completed. • TSG models will be taken care by NPD team (EPD-004342). • Update the Green soft template for submitting the documents for proposed part.	
Regulatory Compliance EPD/ECR Assessment made by: Akanksha Fadtare	
Akanksha Fadtare	**2024.6.06**
Signature	**Date (YYYY.MM.DD)**
Engineering EPD/ECR Assessment made by: Madhu Nalla	
Madhu Nalla	**2024.6.06**
Signature	**Date (YYYY.MM.DD)**
Regulatory Compliance EPD/ECR Assessment approved by: Moriam Raji	
<Insert signature in this location>	*<Click or tap to enter a date.>*
Signature	**Date (YYYY.MM.DD)**
PROJECT VERIFICATION ASSESSMENT (Completed before implementation of the design change)	
(Medical Only) Did any Design verification and/or validation activities produce any unexpected issues of safety or effectiveness? No - Design verification and/or validation activities did not produce any unexpected issues with safety or effectiveness. ☐ All affected reports were verified for change accuracy (CCL, models covered, content, etc.) and all documentation is stored in the Technical File (TF) of the product. ☐ Not a Medical Device **Justification:** • *As per approved test plan, all tests completed, and new part passed. All test results reviewed and approved by Tech pulse, Refer DVR document for test results.* • *FAI: both GFCI and manual updates passed FAI* • *Environmental declaration (REACH, RoHS and Prop65) provided.* • *GS templates to be filled to upload the details in Greensoft tool.*	
Regulatory Compliance EPD/ECR Assessment made by: Akanksha Fadtare	
Akanksha Fadtare	**2024.6.13**
Signature	**Date (YYYY.MM.DD)**
Engineering EPD/ECR Assessment made by: Madhu Nalla	
Madhu Nalla	**2024.6.13**
Signature	**Date (YYYY.MM.DD)**
Regulatory Compliance EPD/ECR Assessment approved by: Moriam Raji	
	**2024.11.13**
Signature	**Date (YYYY.MM.DD)**

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APPENDIX 1 - DEFINITIONS

Control Mechanism	The manner by which the actions of a device are directed. An example of a change in control mechanism would be the replacement of an electromechanical control with a microprocessor control.
Compatibility	Capable of harmonious coexistence; said of two or more medications that are suitable for simultaneous administration without nullification or aggravation of their effects.
Critical to Quality	Components or sub-assemblies that include critical quality parameters that may impact the Quality of the product.
Critical to Safety	Components or sub-assemblies that include Critical to safety parameters. Examples include components listed in Safety Reports (i.e., 61010-1, 60601-1), Compliance Reports (EMC, FCC, IC, etc.). Components responsible for a medical device maintaining essential performance are also considered critical to Safety (see QAP402).
Design history file (DHF)	DHF means a compilation of records which describes the *design* history of a finished device. It is required for medical Class II and Class III FDA devices and medical devices manufactured under ISO 13485.
Device Master Record (DMR)	A device master record (DMR) contains all of the information and specifications needed to *produce* a medical device from start to finish, including instructions for all manufacturing processes, drawings, documented specifications and labeling and packaging requirements. This is required by the FDA for medical devices.
Effectiveness	The extent to which an action or object achieves its intended purpose.
Global Existing Product Change (GEPC)	A singular closed loop approach for change management with standardized terminology for post-design transfer changes to products and processes.
Harm	Physical injury or damage to the health of people
Hazard	Potential source of harm
Intended Use	The term “intended use” means the general purpose of the device or its function, and encompasses the indications for use
In Vitro Diagnostic Device (IVD)	Those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body
Labeling	The term “labeling” means all labels and other written, printed, or graphic matter (1) upon any article or its containers or wrappers, or (2) accompanying such article. This can include, among other things, any user or maintenance manuals and, in some instances, promotional literature.
Material Formulation	The base formulation of a polymer, alloy, etc., plus any additives, colors, etc., used to establish a property or the stability of the material. This does not include processing aids, mold release agents, residual contaminants, or other manufacturing aids that are not intended to be a part of the material, but that could be present as impurities on the final device. An example of a change in material formulation would be a change from a series 300 stainless steel to a series 400 stainless steel. Another example of a change in material formulation would be the addition or subtraction of a chemical or compound to or from a polymer.
Material Type	The generic name of the material from which the device is manufactured. An example of a material type change would be the change from natural latex rubber to synthetic rubber.
Operating Principle	The mode of operation or mechanism of action through which a device fulfills (or achieves) its intended use. An example of a change in operating principle would be using a new algorithm to compress images in a picture archiving and communications system. For an IVD, an example would be a change from immunofluorescence to ELISA.
Packaging	Any wrapping, containers, etc., used to protect, to preserve the sterility of, or to group medical devices.
Performance Specifications	The performance characteristics of a device as listed in device labeling or in finished product release specifications. Some examples of performance specifications are measurement accuracy, output accuracy, energy output level, and stability criteria.
Risk	The combination of the probability of occurrence of harm and the severity of that harm. For the purposes of this document, may relate to either safety or effectiveness (e.g., risk of decreasing device effectiveness).
Safety	The state of being secure or safe from injury, harm, or loss; a judgment of the acceptability of risk–a measure of the probability of an adverse outcome and its severity associated with using a technology in a given situation
Software	The set of electronic instructions used to control the actions or output of a medical device, to provide input to or output from a medical device, or to provide the actions of a medical device. This definition includes software that is embedded within or permanently a component of a medical device, software that is an accessory to another medical device, or software that is intended to be used for one or more medical purposes that performs these purposes without being part of a hardware medical device.
Technical File (TF)	A technical file is a set of documents that describes a product and can prove that the product was designed in accordance with the requirements of a quality management system. This is mandatory for MDR products.
State of the Art	Developed stage of technical capability at a given time as regards products, processes, and services, based on the relevant consolidated findings of science, technology, and experience. Note: • state of the art embodies what is currently and generally accepted as good practice in technology and medicine • Does not necessarily imply the most technologically advanced solution
Unique Device Identifier (UDI)	Unique Device Identifier that is used on a medical device. Specific bar code on labels which are linked to a regulatory authority database (i.e., FDA).
User Interface	A device user interface includes all points of interaction between the product and the user, including elements such as displays, controls, packaging, product labels, and directions for use
Warnings	Warnings describe serious adverse reactions and potential safety hazards that can occur in the proper use or misuse of a device, along with consequent limitations in use and mitigating steps to take if they occur.

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APPENDIX 2 - COMMON SOFTWARE CHANGE TYPES

Infrastructure	Changes are modifications made to the software support system. Examples include but are not limited to: switching compilers, changing programming languages (C to C++, C++ to Java), or changing software drivers or libraries.
Architecture	Changes are modifications to the overall structure of the software. Examples include but are not limited to: porting to a new OS, software changes to support a new hardware platform, and new middleware.
Core algorithm	Changes are modifications made to an algorithm that directly impact or contribute to the device's intended use. Examples include: alarm algorithms on a monitor, a motor control algorithm for an infusion pump, and a detection module and measurement engine algorithm for an IVD.
Clarification of Requirements – No Functionality Change	Changes made to clarify software requirements after a product has received premarket clearance. This clarification may be revised phrasing of an existing requirement or creation of a new requirement altogether, without changing or adding functionality.
Cosmetic Changes – No Change to Functionality	Changes made to the appearance of the device that do not impact the clinical use of the device. For example, changing the company logo that is displayed on the background of every screen could involve modifying multiple software modules; while the number of modules impacted may be large, it is unlikely that the intended change could significantly impact the device's safety and effectiveness or intended use
Re-engineering	Common software maintenance techniques. "Reengineering" is defined as the examination and alteration of software to reconstitute it in a new form, and includes the subsequent implementation of the new form. It is often undertaken to replace aging legacy software.
Refactoring	"Refactoring" is a disciplined technique for restructuring a software program's internal structure without changing its clinical performance specification. Refactoring seeks to improve a program structure and its maintainability. In general, reengineering often results in broader and more complex changes, while refactoring is often narrower in scope and less complex.