

FENG093

TITLE: Regulatory Compliance Impact Assessment - Template

REV.: C

REGULATORY COMPLIANCE IMPACT ASSESSMENT				
Number:	# associated with	h change.>	CAPA Asso	ociated: <select one.=""></select>
Level: L2L			CAPA ID: <	Insert CAPA ID>
Problem Statement / Change Scope				
<identify and="" assessed="" be="" being="" change="" design="" engineering="" is="" made.="" or="" problem="" scope="" statement="" that="" the="" to="" why=""></identify>				
Description of the Product				
<insert a="" accessories="" and="" brief="" change.="" description="" in="" of="" product="" scope="" the="" this=""></insert>				
Affected Product Family / Model(s) and Accessories (Do not embed documents for PDF visibility)				
Models:				
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 "other"="" chosen.="" if="" in="" is=""> Name of OEM (if applicable): <name oem="" of=""></name></fill></choose>				
Manufacturing Site: □AVL □ MAR □ LSB □ OHA □ SNG □ Other □OEM □ CM (External)				
Other (if applicable): <fill "other"="" chosen.="" if="" in="" is=""> Name of OEM (if applicable): <name oem="" of=""> CM (External – if applicable): <name cm="" of=""></name></name></fill>				
Design is Copy Exact: <choose an="" item.=""></choose>				
New models SKUs to be created in scope of this project:				
<if a="" are="" be="" created,="" field.="" in="" n="" new="" no="" place="" skus="" there="" this="" to=""></if>				
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.				
N. America	EMEA	LATA	M	APAC
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	Number: <insert change="" change.="" common="" design="" in="" l2l="" level:="" of="" recessories="" ring="" scope="" sign="" so="" the=""> If by this design change with descriptions (if recessories has been changed) are (if applicable): <fill "other"="" <name="" ble):="" chose="" cm="" if="" in="" is="" of="" oha="" other="" sng="" to="" □=""> Is project: N/A in this field.> I Known Markets Seed on the Intended Unice types, all Device Ty N. America ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑ ☑</fill></insert>	Number: <insert #="" assessories="" associated="" be="" change="" change.="" design="" in="" is="" l2l="" level:="" of="" ring="" scope="" that="" this="" to="" with=""> Accessories (Do not embed documents assign change.> A by this design change. If no accessories are associated with the product of the shows the SKUs and which device types the action of the shows the SKUs and which device types the action of the shows the SKUs and which device types the action of the shows the SKUs and which device types the action of the shows the SKUs and which device types the action of the shows the SKUs and which device types the shows the sho</insert>	Number: <insert #="" associated="" change.="" with=""> Level: L2L ring design change scope that is to be assessed and why the coessories in scope of this change.> Accessories (Do not embed documents for PDF visibility sign change.> At by this design change. If no accessories are impacted, state at shows the SKUs and which device types they fall under). If the product has SKUs that for at shows the SKUs and which device types they fall under). If the product has SKUs that for at shows the SKUs and which device types they fall under). If the product has SKUs that for at shows the SKUs and which device types they fall under). If the product has SKUs that for at shows the SKUs and which device types they fall under). If the product is shown the SKUs and which device types of OEM (if applicable): All in if "Other" is chosen.> Name of OEM (if applicable): All in if "Other" is chosen.> Name of OEM (if applicable): All in this field.> All Known Markets Accessories in scope of this change.> Accessories in scope of this change. Accessorie</insert>	Number: <insert #="" associated="" change.="" with=""> Level: L2L CAPA ID: < CAPA ID: <</insert>