Handicare PPAP Submission Requirements & Coaching QOP-G742-06

23rd May 2023

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Production Part Approval Process (PPAP)

What is PPAP?

The **P**roduction **P**art **A**pproval **P**rocess is a framework of requirements for series parts used in the manufacturing environment. PPAP is used to prove the quality of suppliers and their manufacturing processes.

P P A P

Production **Part** **Approval** **Process**

The purpose of PPAP is for suppliers to demonstrate that they have understood the customer's design and in series production, to produce products that consistently meet all requirements and specifications, while maintaining the production rate.

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Production Part Approval Process (PPAP)

Benefits of PPAP:

- Helps maintain design integrity.
- Identifies issues early for resolution.
- Reduces warranty charges and prevent costs of poor quality
- Assists in managing supplier changes
- Prevents use of unapproved and non-conforming parts and process
- Identifies suppliers that need more development)
- Improves the overall quality of the product & customer satisfaction

The Production Part Approval Process (PPAP) is fundamentally a team based activity.

The PPAP documentation is laid out so that the first sheet is the first stage, the second sheet the second step and so on… This Power Point is laid out in the same manner.

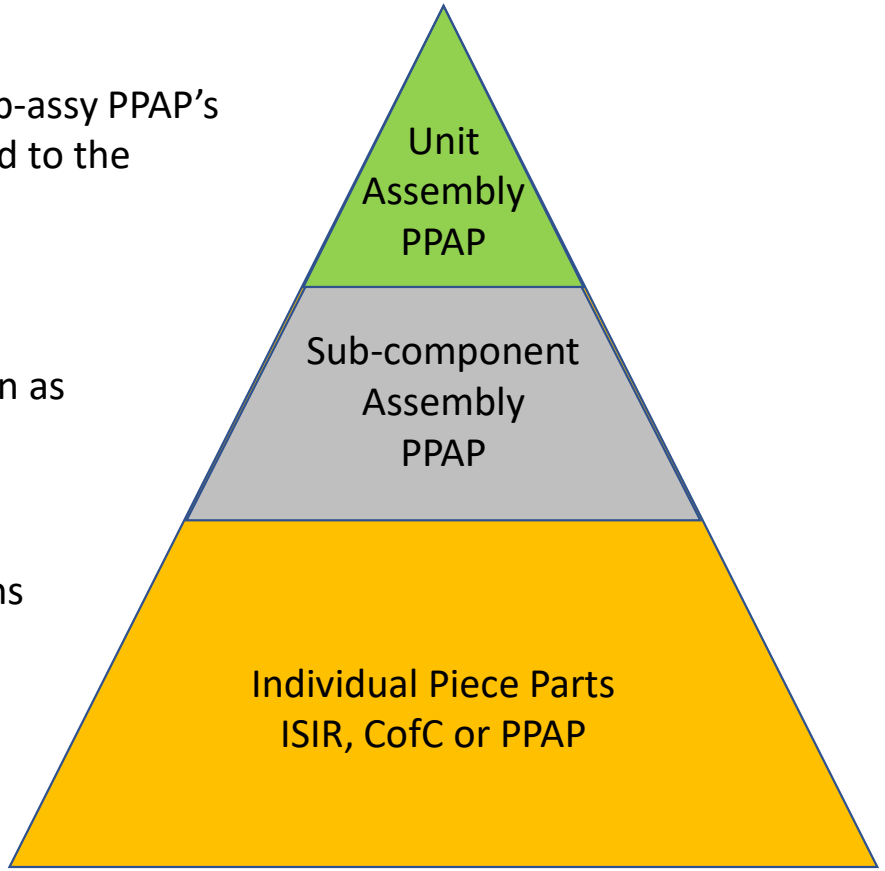
Production Part Approval Process (PPAP)

How does PPAP build?

A Unit or System PPAP we create a document that draws on the Sub-assy PPAP's
Any individual piece parts PPAP's not previously referenced is added to the documentation pack

Sub assy PPAP's draw on the individual piece part PPAP submission
Any individual piece part PPAP's are reference in the documentation as evidence

Each individual piece part should be certified confirming dimensions and functions.
For Of the shelf items, the supplier or Handicare shall have a CofC (Certificate of Conformity)



Using PPAP to control a change for an up-issue in a part or system

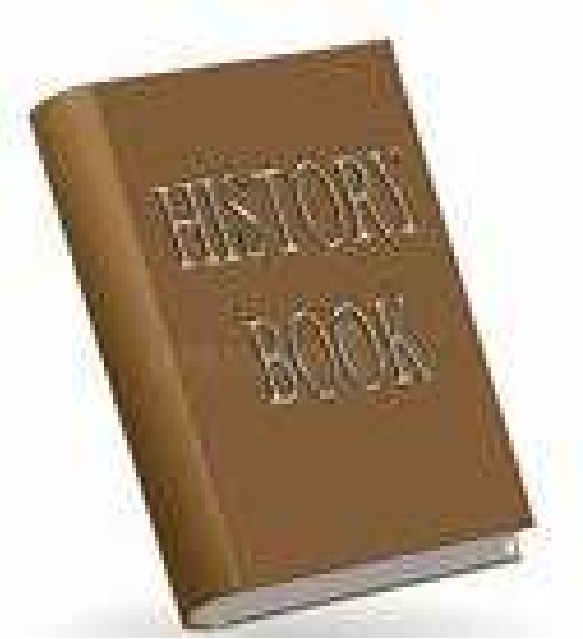
PPAP can record the change history to an individual part or system but not when it was introduced. That is the APQP process

Changes can be traced back using the ECN process and drawing issue level changes.

Can track a single or multi feature/dimension changes

Use the previously accepted documentation as your base line.

Only document the up issue feature. No need to remeasure existing unchanged features/dimensions



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Production Part Approval Process (PPAP)

Using PPAP to control a change for an up-issue in a part or system

As described in the procedure QOP-G742 03 PPAP Process submission matrix. There are elements that will NOT be required to be completed providing that there is an acceptable base line PPAP submission.

Elements that shall not require resubmission providing the part number has not changed. I.e. **Feasibility, Process Flow Plan, Packaging Approval and PFMEA.**

To be considered for inclusion
Appearance Approval Report - if the change is customer visible
Process Capability - if the change feature is not a CTQ or deemed critical by Handicare R&D team

Mandatory for inclusion
Drawing, Control Plan (reflecting the change), FAI (First Article Inspection) & Material certification

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Production Part Approval Process (PPAP)

When to Raise a Handicare PPAP submission. Guidance Notes:

A new part(s) request.

This applies if there is a new part that is being developed by an existing supplier.
Can also apply should Handicare be moving an existing qualified component or process to a different provider

A change to the existing product or material that may affect Fit, Form or Function.

This captures a request or design change of material

A change to the production process. (Handicare must be Informed)

This is when an occasion arises when the usual or stated machine or process is changed, even if temporary. Could be due to a breakdown or supplier process improvement. It is important for Handicare to be informed and understand that there are no implications due to the changes that may affect the end-product and system.

Interruptions to production lasting longer than 12 months.

This is to cover a supplier making a year's stock and then there being little done with the tool or to check the tooling maintenance so when called upon it supplies conforming product.

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Production Part Approval Process (PPAP)

When to Raise a Handicare PPAP submission. Guidance Notes:

A change to tools or Machines or Machines location (Handicare must be Informed)

This is in the event of a supplier moving or relocating a machine within the original manufacturing plant or should the supplier make the component or process at another site

A change to/at sub-suppliers. (Handicare must be Informed)

The supplier should declare to Handicare if there is a change of the supplier's material or processes

At the request of the customer (Handicare).

Can be requested by Handicare to support a major quality or manufacturing disruption event corrective action

N.B. PPAP package should only be issued to the supplier once they are ready to manufacture of productionised Tooling or Processes at production rate

The supplier, during development, can supply sample parts using the FAI documents in the PPAP Pack or use ISIR. Acceptance of the FAI or ISIR samples DOES NOT allow for full production to commence.

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Production Part Approval Process (PPAP)

When to Raise a Handicare PPAP submission:

- A new part(s) request.
- A change to the existing product or material that may affect Fit, Form or Function.
- A change to the production process. (Handicare must be Informed)
- Interruptions to production lasting longer than 12 months.
- A change to tools or Machines or Machines location (Handicare must be Informed)
- A change to/at sub-suppliers. (Handicare must be Informed)
- At the request of the customer (Handicare).
- When the supplier process is ready to manufacture of productionised Tooling or Processes

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Production Part Approval Process (PPAP)

The Elements in a Handicare PPAP Submission?

- Handicare's FULL PPAP submission contains 11 elements
- If required, additional supporting documented evidence of the process or component controls may be requested
- Our PPAP has 3 different levels of submission requirements operates (1, 2 or 3) which is communicated to the supplier at the start of the consultation process.
- The description of the level requirement can be found in the procedure that supports this process.

STEP	START	ROLES & PRESPONSIBILITIES
1	Part Approval Request and Requirement (PAR)	Led by R&D and completed by the Handicare team and with the supplier
2	Feasibility Review	Supplier generates and reviews the document with Handicare to ensure full understanding of all product/process expectations on the official drawing
3	Review Process Flow Plan	The Process Flow is completed by the supplier. It identifies all steps and sequences in the fabrication process, including incoming components
4	Review FMEA	Process **Failure Mode and Effect Analysis** (PFMEA) document is a supplier owned and generated document that evaluates and assesses the risk of the steps of the production process and mitigates areas of high risk areas.
5	Review Control Plan	The Supplier generated plan defines the controls required to ensure a consistent part/process. It is reviewed with Handicare
6	Review FAI First Article Submission	Supplier generates a document that is reviewed by Handicare Quality, Manufacturing and R&D before moving to next stage
7	Review Process Capability @ Suppliers Site	Larger samples taken to prove the process is capable and stable before going to full production. Results reviewed by Handicare
8	Review Appearance Approval Report (AAR)	Results reviewed with Handicare Domestic Quality team to ensure customer expectations are fully understood
9	Material Certification	The suppler shall add material certification for traceability purposes and shall perform test to ensure compliance to any stated product materials chemical, physical or metallurgical requirements are specified
10	Confirm Packaging requirement Internally & Externally	All packaging, labelling & handling aspects are considered against Handicare H&S, ergonomic and environmental requirements
11	Review and Sign Part Submission Warrant (PSW)	Completed by the Handicare, Quality, Purchase and Manufacturing teams after agreement of the FAI submission.
12	Checking Aids Additional requirement if requested by Handicare	Supplier generates test reports or output data to support compliance of electrical, electro-mechanical components
13	MSA (Measurement System Analysis) Additional requirement if requested by Handicare	Supplier generates MSA report to demonstrate process repeatability and reproducibility
	FINISH	

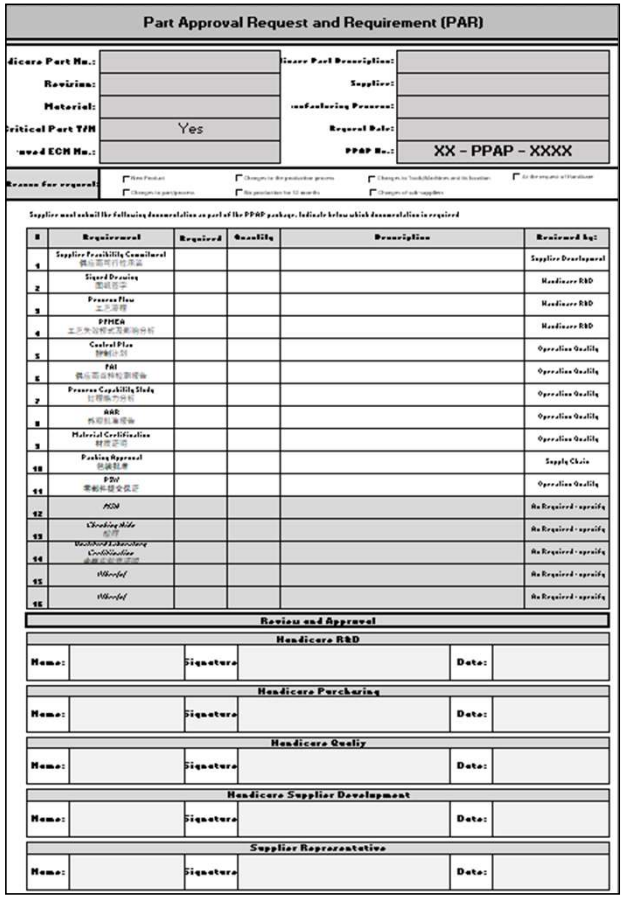
Step 1

Handicare PPAP Element - Part Approval Request and Requirement (PAR)

PAR - Step owner:- R&D supported by the Handicare team

Responsibilities:

1. Identifies the expectations and the requirement for the PPAP submission
2. Supply the latest official revision level drawing to ensure the supplier fully understands the intended design. Even through part or system development stages
3. Issues the PPAP its own you unique number and log the activity into the system
4. Identify the requirements and quantities for the PPAP submission
5. Sense check document prior to review and approval by the Handicare stakeholders
6. Handicare, R&D, Purchasing, Domestic Quality, Supplier Development and Suppliers representative(s) sign and date of the PAR document to acknowledge the requirement



Part Approval Request and Requirement (PAR)

Yes

XX – PPAP – XXXX

Review and Approval

Handicare R&D

Handicare Purchasing

Handicare Quality

Handicare Supplier Development

Supplier Representative

Step 1

Handicare PPAP Element - Part Approval Request and Requirement (PAR)

PAR - Handicare PPAP Document Pack Check

1. That the header information corresponds to the drawing i.e. material, revision level and Purchase Order
2. Check the ECN No is on the system
3. Check the document has an unique PPAP No and is on the PPAP log
4. Confirm the criticality box on the header is answered
5. The reason for the PPAP submission has been checked
6. All requirements and quantities have been checked
7. Post the Handicare stakeholder review, all names, signatures and dates have been completed.
8. That the suppliers representative(s) have also signed and dated the PAR document

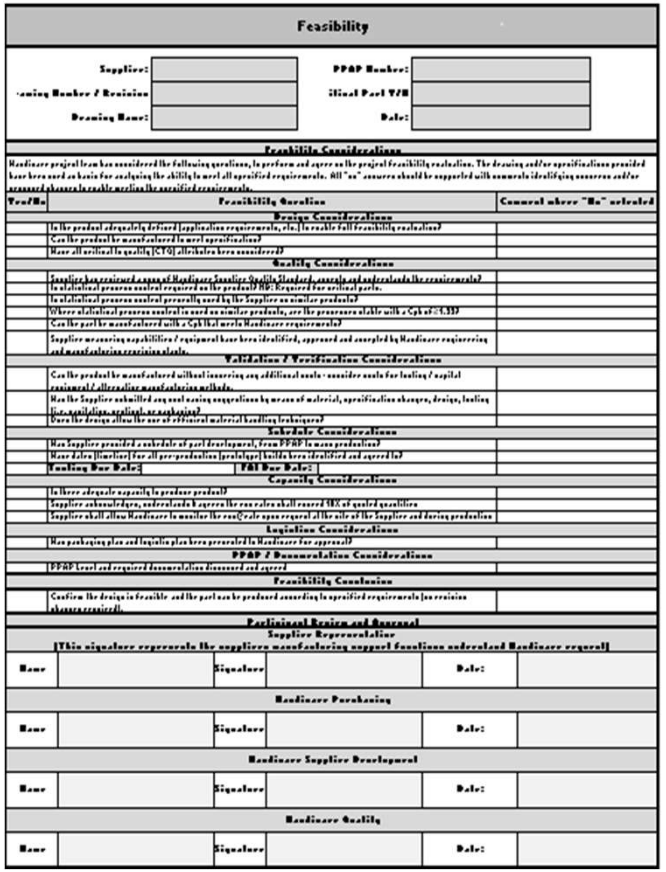
Step 2

PPAP Element;- Feasibility Review

FEASIBILITY - Step owner:- Supplier Development

Responsibilities:

1. The Feasibility questionnaire should be completed with Handicare Supplier Development or representative.
2. All questions need to be reviewed to ensure that the requirement is fully understood from the very start project or a process or part change.
3. Ensure drawings, models, specifications, measurement evaluation method and the final finished appearance are fully understood and achievable.
4. Confirm all CTQ and features considered as critical by Handicare R&D are identified and acknowledged for the capability study process and on-going measurement surveillance during the feasibility review
5. CTQ's must be off a productionised processes for evaluation.
6. Confirm and agree the PPAP submission date.
7. Raise any potential design changes to alleviate identified issues prior to the start of Production and the PPAP submission.
8. Once the document is submitted by the supplier, the Handicare team shall review sign and date to acknowledge



Feasibility

Supplier:
Drawing Number / Revision
Drawing Name:
PPAP Number:
Date:

Feasibility Considerations

Yes/No	Feasibility Question	Comment where "No" selected
	Design Considerations	
	Is the product adequately defined (application requirements, etc.) to enable full feasibility evaluation?	
	Can the product be manufactured to meet specifications?	
	Have all critical to quality (CTQ) attributes been considered?	
	Quality Considerations	
	Supplier has received a copy of Handicare Supplier Quality Standard, accepts and understands the requirements?	
	Is statistical process control required on the product/PPAP required for critical parts.	
	Is statistical process control presently used by the Supplier on similar products?	
	Where statistical process control is used on similar products, are the processes stable with a Cpk of ≥1.33?	
	Can the part be manufactured with a Cpk that meets Handicare requirements?	
	Supplier measuring capabilities / equipment have been identified, approved and complied by Handicare engineering and manufacturing engineering teams.	
	Validation / Verification Considerations	
	Can the product be manufactured without incurring any additional tools - consider tools for tooling / capital equipment / alternative manufacturing methods.	
	Has the Supplier submitted any cost saving suggestions by means of material, specification changes, design, tooling (i.e., capitalise, optional, or engineering)	
	Does the design allow the use of additional material handling techniques?	
	Schedule Considerations	
	Has Supplier provided a schedule of part development, from PPAP to mass production?	
	Have dates (timeline) for all pre-production (prototype) builds been identified and agreed to?	
	Tooling Due Date: T01 Due Date:	
	Capacity Considerations	
	Is there adequate capacity to produce product?	
	Supplier acknowledges, understands & agrees the run rates shall exceed 10X of quoted quantities	
	Supplier shall allow Handicare to monitor the run/Cpk rate upon request at the site of the Supplier and during production	
	Logistics Considerations	
	Has packaging plan and logistics plan been presented to Handicare for approval?	
	PPAP / Documentation Considerations	
	PPAP Level and required documentation discussed and agreed	
	Feasibility Conclusion	
	Confirm the design is feasible and the part can be produced according to specified requirements (no revision changes required).	

Preliminary Review and Approval

Supplier Representative

(This signature represents the suppliers manufacturing support functions understand Handicare request)

Name		Signature		Date:	

Handicare Purchasing

Name		Signature		Date:	

Handicare Supplier Development

Name		Signature		Date:	

Handicare Quality

Name		Signature		Date:	

Step 2

PPAP Element;- Feasibility Review

Feasibility Review - Handicare PPAP Document Pack Check – SUPPLIER DEVELOPMENT and the HANDICARE TEAM

1. That the header information corresponds to the drawing
2. Check the unique PPAP
3. Confirm the criticality box on the header is answered
4. The unique PPAP number is consistent with records and other documentation
5. In the Yes/No column, all questions are answered
6. Any “No” answers must have a supporting comment
7. Post the Handicare stakeholder review, all names, signatures and dates have been completed
8. Post the Handicare and Participant Review & Approval ensure all names, signatures and dates have been completed

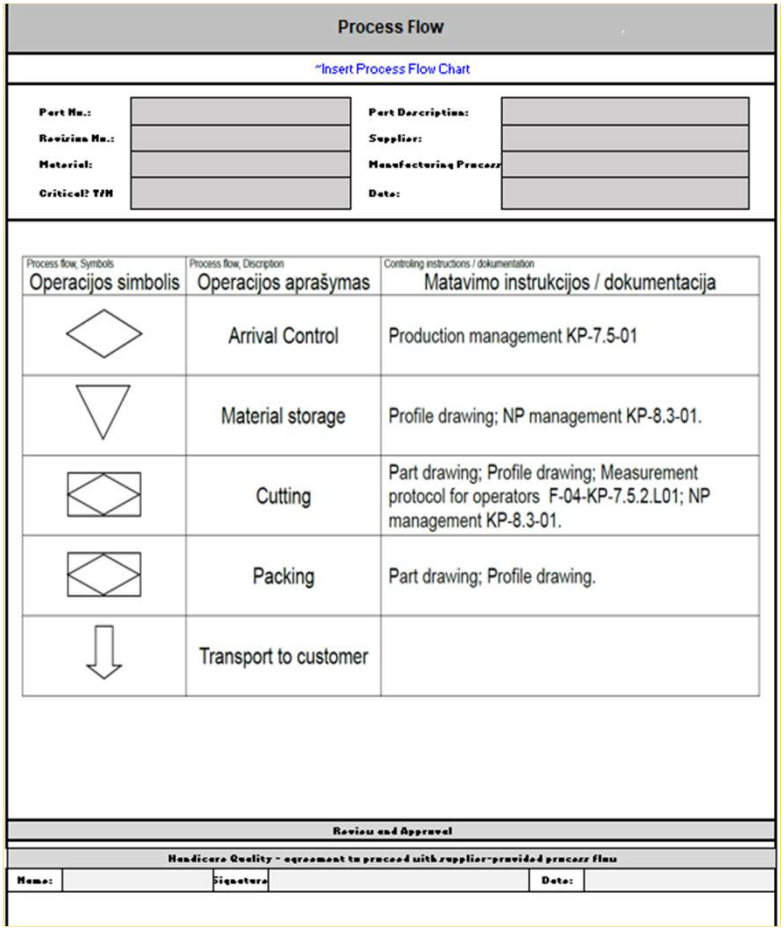
Step 3

PPAP Element- Process Flow

PROCESS FLOW - Step owner:- Supplier, Handicare Supplier Development

Responsibilities:

1. The Process Flow is completed by the supplier. It identifies all steps and sequences in the fabrication process, including incoming components
2. It should provide detail on all controls from receipt of raw material or product to when it leaves the facility for out sources processes through to delivery to Handicare
3. Should be supported by the suppliers control plan and the organisations work instruction and build records
4. Submitted to Handicare



Process Flow

*Insert Process Flow Chart

Part No.:		Part Description:	
Revision No.:		Supplier:	
Material:		Manufacturing Process	
Critical? Y/N		Date:	

Process flow, Symbols Operacijos simbolis	Process flow, Discription Operacijos aprašymas	Controling instructions / dokumentation Matavimo instrukcijos / dokumentacija
	Arrival Control	Production management KP-7.5-01
	Material storage	Profile drawing; NP management KP-8.3-01.
	Cutting	Part drawing; Profile drawing; Measurement protocol for operators F-04-KP-7.5.2.L01; NP management KP-8.3-01.
	Packing	Part drawing; Profile drawing.
	Transport to customer	

Review and Approval

Handicare Quality - agreement to proceed with supplier-provided process flow

Name:		Signature		Date:	

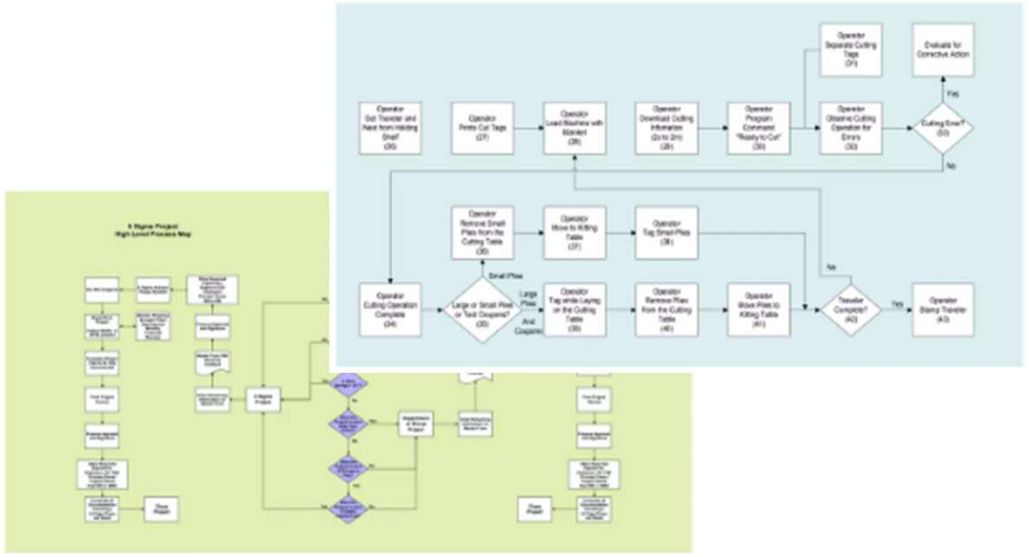
Step 3

PPAP Element- Process Flow

PROCESS FLOW

Handicare Process Flow PPAP Document Pack Check – SUPPLIER DEVELOPMENT

1. Process Flow must identify each step in the process
2. Should include abnormal handling processes
   - Scrap
   - Rework
3. Must also include
   - Receiving of raw material
   - Part Manufacturing
   - Offline inspection & checks
   - Assembly
   - Shipping

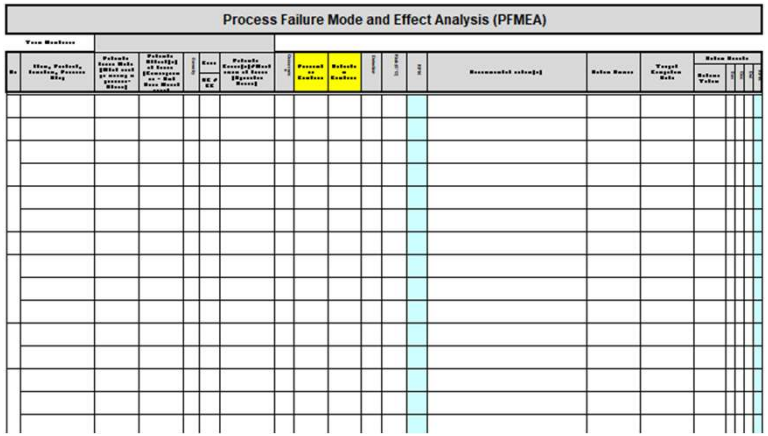


Handicare PPAP Document Pack Check - INTERNAL

1. That the header information corresponds to the drawing
2. Corresponds to stated revision level
3. Handicare, Review & Approve and have endorsed the sheet in the PPAP to reflect its status
4. Check the criticality box on the header has been checked

Step 4

PPAP Element- PFMEA



PFMEA - Step owner:- Supplier, Handicare Supplier Development

Responsibilities:

1. Process **Failure Mode and Effect Analysis** (PFMEA) is owned and generated by the supplier.
2. Determine if PFMEA is Generic or Specific in origin
3. The Handicare Supplier Development team or Handicare R&D, Engineering function or its delegate shall to review the document at the suppliers premises to ensure that the document exists and for its currency.
4. The document shall be reviewed alongside the suppliers control plan an all other associated documentation relating to the process or part number

Step 4

PPAP Element- PFMEA

PFMEA - Handicare PPAP Document Pack Check – SUPPLIER DEVELOPMENT & R&D

1. The Handicare Supplier Development team, R&D function or its delegate review the (PFMEA), at the top level and that it can be linked to the Part No or Process Operation number.
2. PPAP (PFMEA) template has been endorsed to reflect its status by Handicare representative
3. Can be accepted even if it is NOT on the Handicare PPAP/PFMEA template
4. Review the document header information against control plan header information and the drawing and its revision level
5. Check RPN numbers are under the stated limits
6. Any high RPN's are supported by "Recommended Actions" have an Owner, Target date and a revised/improved RPN number
7. Any high RPN concerns are carried over into the control plan
8. Make sure that all critical failure modes are addressed
    - Safety
    - Fit, Form & Function
    - Material Concerns

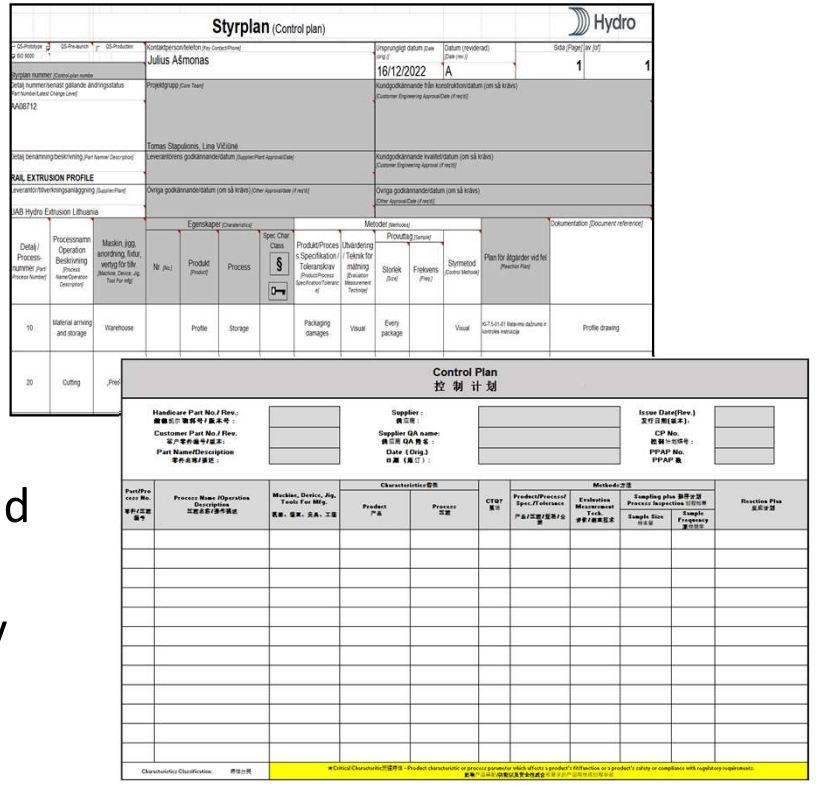
Step 5

PPAP Element- Control Plan

Control Plan – Step owner – Supplier, Handicare Supplier Development

Responsibilities:

1. The supplier shall create and submit the Control Plan that describes the controls of critical inputs that meet the Handicare expectations and Design requirements
2. Determine Control Plan is Generic or Specific in origin
3. The Control Plan shall be reviewed by the Handicare Supplier Development team, Quality & Operations teams for is effectiveness and currency
4. The Control Plan shall contain detailed reaction plans should there be an NOK condition identified.
5. Where possible review at the suppliers premises preferably in conjunction with the PFMEA submission



Step 5

PPAP Element- Control Plan

Control Plan - Handicare Document review – SUPPLIER DEVELOPMENT & QUALITY

1. Control Plan document header has been completed and can be linked to the PFMEA, Item, Product, Function, Process Step and unique the PPAP number is present
2. The Control Plan can be accepted even if NOT on the Handicare Control Plan template. It should be pasted in to the template if possible.
3. That the Control Plan has been reviewed by the Handicare Supplier Development team, R&D, Engineering function or its delegate along side the PFMEA for its currency and the sheet in the PPAP has been endorsed to reflect its status

Handicare PPAP Document Pack Check – INTERNAL and DOMESTIC QUALITY

1. That the header information corresponds to the drawing
2. Corresponds to stated revision level
3. Handicare, Review & Approve and have endorsed the sheet in the PPAP to reflect its status
4. That a copy if possible has been pasted into the template

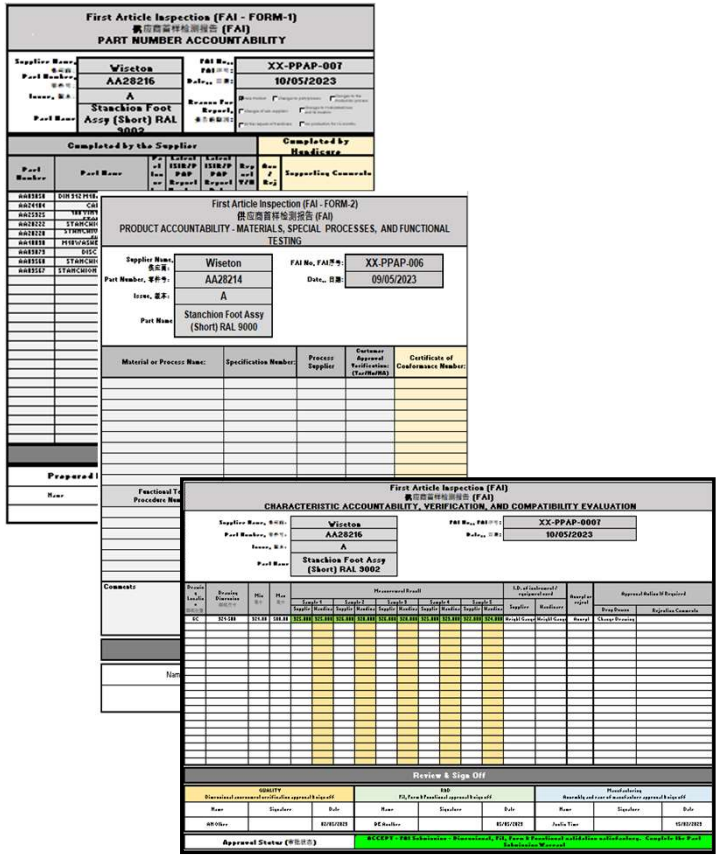
Step 6

PPAP Element- FAI (First Article Inspection)

FAI (First Article Inspection) – Step owner – Supplier, Handicare Domestic Quality

Responsibilities for FAI

1. The supplier shall submit an FAI report for a minimum of 5 pieces or assemblies
2. Main elements of a FAI submission consists of 3 Forms and a capture sheet for supporting documentation
   - FORM-1, Part Number Accountability
   - FORM-2, Product Accountability- Materials, Special Processes & Functional Testing
   - FORM-3, Characteristic accountability, Verification & Compatibility Evaluation
     - Material certification relating to the samples
     - Ballooned or Marked up print relating to drawing features



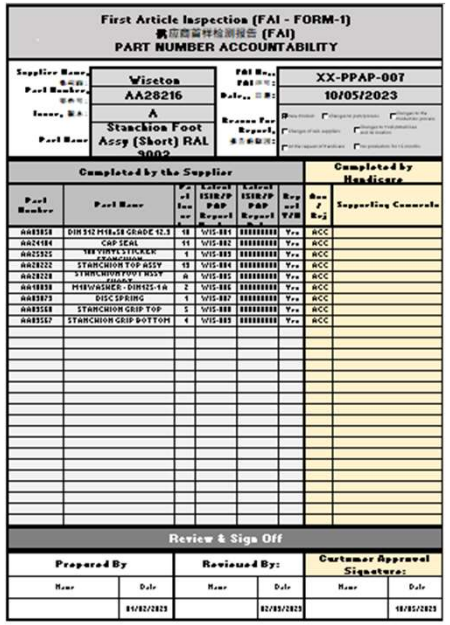
Step 7

PPAP Element- FAI (First Article Inspection ASSEMBLY)

FAI (First Article Inspection) – Step owner – Supplier, Handicare Domestic Quality

FAI - FORM-1, Part Number Accountability

1. The supplier shall complete and submit the FORM-1 that corresponds to the x5off pieces or assemblies for the FAI submission
2. List of a FAI submission details…
   - For a component list the SINGLE piece part number for the FAI submission
   - For an ASSEMBLY list all of the piece parts involved in the assembly.
3. For an assembly, the supplier shall attach a PDF copy of the relevant approval documentation for each piece part listed. The lower level documents can be embedded into FAI Appendix Sheet for review by Handicare
   - Acceptable Evidence…
     - An ISIR to the required piece part issue level.
     - A PSW of the required piece part at the required issue level.
     - For catalogue items, a copy of the material certificate and/or CofC (Certificate of Conformity)
4. Complete the Prepared and Reviewed by sections before submission to Handicare



First Article Inspection (FAI - FORM-1)
PART NUMBER ACCOUNTABILITY

Supplier Name	Wisetos	FAI Reg.	XX-PPAP-007
Part Number	AA28216	Date	10/05/2023
Issue	A	Reason For Report	
Part Name	Stanchion Foot Assy (Short) RAL 9002		

Completed by the Supplier						Completed by Handicare	
Part Number	Part Name	No. of Iss. or	Latest ISIR/PSW Report No.	Latest ISIR/PSW Report No.	Req. incl Y/N	Acc / Rej	Supporting Comments
AA03858	DIN 912 M10x58 GRADE 12.9	10	WIS-001	[redacted]	Yes	ACC	
AA24184	CAP SEAL	11	WIS-002	[redacted]	Yes	ACC	
AA25522	WARNING STICKER	1	WIS-003	[redacted]	Yes	ACC	
AA28222	STANCHION TOP ASSY	13	WIS-004	[redacted]	Yes	ACC	
AA28228	STANCHION FOOT ASSY (SHORT)	8	WIS-005	[redacted]	Yes	ACC	
AA10838	M10 WASHER - DIN125-1A	2	WIS-006	[redacted]	Yes	ACC	
AA03873	DISC SPRING	1	WIS-007	[redacted]	Yes	ACC	
AA03568	STANCHION GRIP TOP	5	WIS-008	[redacted]	Yes	ACC	
AA03567	STANCHION GRIP BOTTOM	4	WIS-009	[redacted]	Yes	ACC	

Review & Sign Off

Prepared By		Reviewed By:		Customer Approval Signature:	
Name	Date	Name	Date	Name	Date
	01/02/2023		02/05/2023		10/05/2023

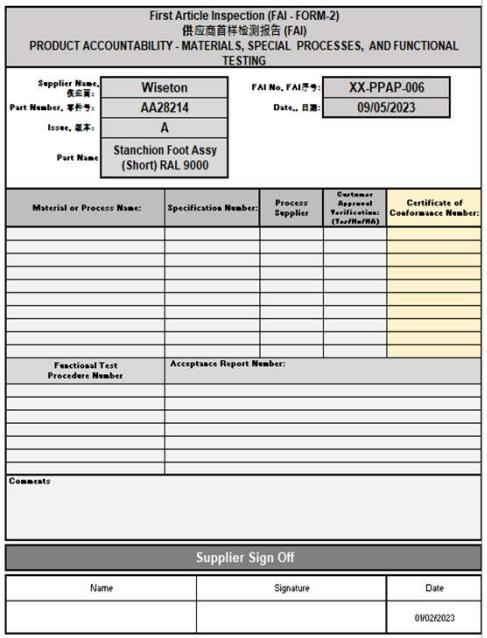
Step 6

PPAP Element- FAI (First Article Inspection ASSEMBLY)

FAI (First Article Inspection) – Step owner – Supplier, Handicare Domestic Quality

FAI - FORM-2, Product Accountability- Materials, Special Processes & Functional Testing

1. The supplier shall complete and submit the FORM-2 that corresponds to the x5off pieces or assemblies for the FAI submission
2. List any of the of the Materials, Special Processes & Functional Testing that support the FAI submission that relate to the design requirement .
    - Examples for consideration
        - Raw materials
        - Heat treatment that can affect performance
        - Endurance Testing
        - Functional Testing
        - Laser Etching
        - Painting and Plating processes that can affect performance
4. Complete the Reviewed by section before submission to Handicare



First Article Inspection (FAI - FORM-2)
供应商首样检测报告 (FAI)
PRODUCT ACCOUNTABILITY - MATERIALS, SPECIAL PROCESSES, AND FUNCTIONAL TESTING

Supplier Name, 供应商:	Wiseton	FAI No, FAI序号:	XX-PPAP-006
Part Number, 零件号:	AA28214	Date,, 日期:	09/05/2023
Issue, 版本:	A		
Part Name	Stanchion Foot Assy (Short) RAL 9000		

Material or Process Name:	Specification Number:	Process Supplier	Customer Approval Verification: (Yes/No/NA)	Certificate of Conformance Number:

Functional Test Procedure Number	Acceptance Report Number:

Comments

Supplier Sign Off

Name	Signature	Date
		01/02/2023

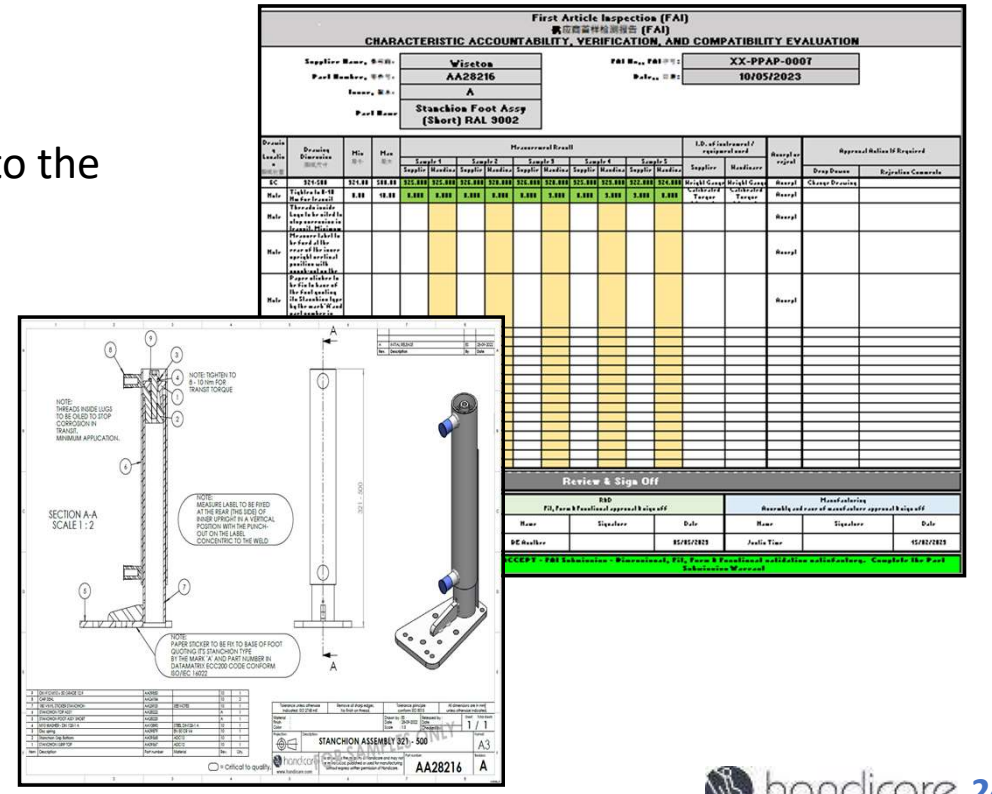
Step 6

PPAP Element- FAI (First Article Inspection ASSEMBLY)

FAI (First Article Inspection) – Step owner – Supplier, Handicare Domestic Quality

FAI - FORM-3, Characteristic accountability, Verification & Compatibility Evaluation

1. The supplier shall complete and submit the FORM-3 that corresponds to the x5off pieces or assemblies for the FAI submission
2. List all the features contained on the drawing the relate to the design
   - To be recorded
     - All dimensions regarding the finished assembly
     - Measurement equipment used
     - All Note details


First Article Inspection (FAI)
CHARACTERISTIC ACCOUNTABILITY, VERIFICATION, AND COMPATIBILITY EVALUATION
Supplier Name: Wiseton
Part Number: AA28216
Issue: A
Part Name: Stanchion Foot Assy (Short) RAL 9002
FAI No.: XX-PPAP-0007
Date: 10/05/2023
Review & Sign Off

Step 6

PPAP Element- FAI (First Article Inspection)

FAI - Handicare PPAP Document Pack Check – DOMESTIC QUALITY

1. That the header information corresponds to the drawing on ALL forms 1,2 & 3 and the Appendix Sheet
2. All elements of the FAI pack are available
3. Dimensional check concurs with suppliers results (No Red results)
4. Gauging or Measurement equipment has been declared
5. For Catalogue or Stockist items i.e. grease, washers, gaskets and seals etc Handicare only require a copy of the
   - The PO for traceability
   - Certificate of Conformity (CofC)
   - Material certification
6. For an Assembly FAI, all child part packs/front sheets are attached and available

N.B.

Acceptance of the FAI samples DOES NOT allow for full production to commence. This only allows for the submissions to go forward for Fit, Form and Functional evaluation testing

Step 6

PPAP Element- FAI (First Article Inspection)

FAI - Handicare PPAP Document Pack Check – DOMESTIC QUALITY, R&D & MANUFACTURING Sign Off. APPLIES TO BOTH COMPONENT AND ASSEMBLY FAI's

The FAI Sign off is completed in 3 stages and is the same for both Component and Assembly FAI submissions

1. The **Domestic Quality** team shall complete the Dimensional assessment section. If satisfactory the parts and documentation are sent to R&D for Fit, Form & Functional approval
2. On completion of any Fit, Form & Functional and Endurance testing for the same component or assembly, **R&D** complete there sign off and send the documentation pack to Manufacturing to confirm, assembly and ease of manufacture approval
3. Once **Manufacturing** confirms the ease of manufacture and assembly is acceptable, final approval for the FAI is highlighted with the instruction to complete the PSW.
4. Manufacturing sign off and send the documentation pack to back to Domestic Quality to close off the pack and record the FAI status on the tracking log.

QUALITY Dimensional assessment verification approval & sign off		
Name	Signature	Date
Duncan Walker	D. H R Walker	12/04/2023
Approval Status (审批状态)		

R&D Fit, Form & Fucntional approval & sign off		
Name	Signature	Date
Paul Sykes	P.Sykes	
ACCEPT - FAI submission. Move to R&D/Manuf		

Manufacturing Assembly and ease of manufacture approval & sign off		
Name	Signature	Date
Dejan Kedves	D.Kedves	30/04/2023
validation satisfactory. Complete the Part Submission Warrant		

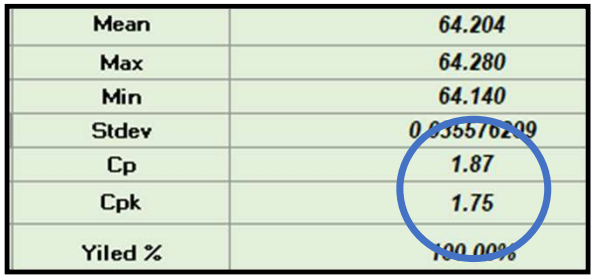
Step 7

PPAP Element- Process Capability

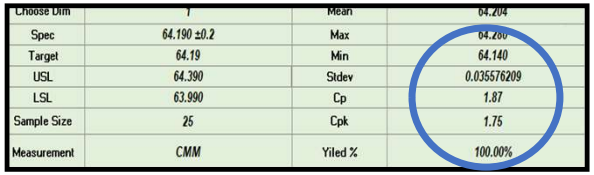
Process Capability – Step owner – Supplier, Supplier Development

Responsibilities:

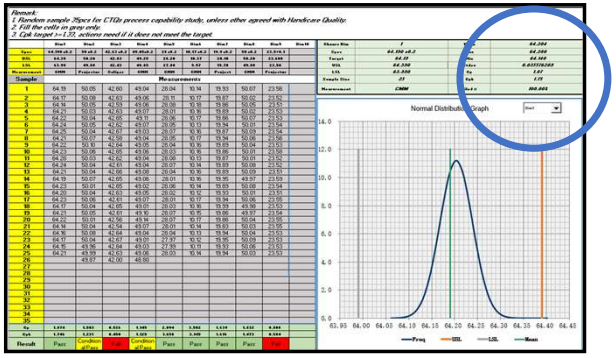
1. The suppler shall submit/provide Process capability measurement data for a minimum of 30 pieces made from production set up on all CTQ features and those features considered as critical by R&D during the feasibility review
2. In case of Moulding or castings the above applies of each cavity
3. In case of Mouldings measurement is taken prior to applying the textured finish (if applicable)
4. For machined items measurement data for a minimum of 30 pieces from each of the proposed machining centres and ideally from each shift (For example: Day/night shifts)
5. The process capability data shall across all the drawing dimensions
6. Any features identified as Critical To Quality (CTQ's) shall have on-going measurement surveillance supported regular periodic measurement monitored using Statistical Process Control (SPC) or via checking fixtures



Mean	64.204
Max	64.280
Min	64.140
Stdev	0.035576209
Cp	1.87
Cpk	1.75
Yiled %	100.00%



Choose Dim	1	Mean	64.204
Spec	64.190 ±0.2	Max	64.280
Target	64.19	Min	64.140
USL	64.390	Stdev	0.035576209
LSL	63.990	Cp	1.87
Sample Size	25	Cpk	1.75
Measurement	CMM	Yiled %	100.00%

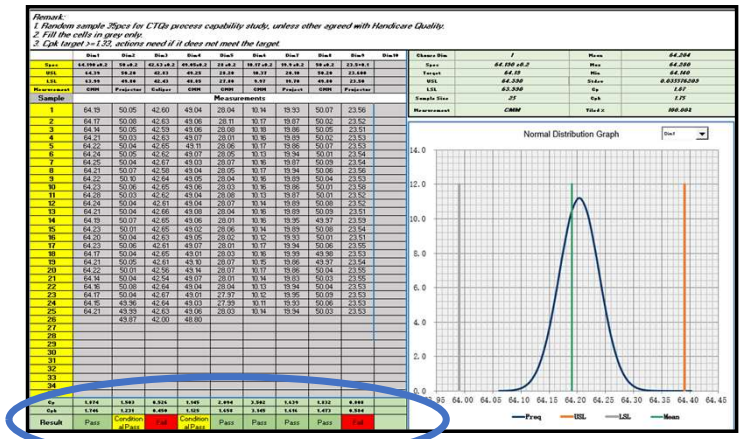


Step 7

PPAP Element- Process Capability

FAI - Handicare PPAP Document Pack Check – SUPPLIER DEVELOPMENT & QULAITY

1. That the header information corresponds to the drawing
2. All CTQ dimensions and any features identified as critical by Handicare R&D also appear on the capability sheet
3. The PPAP should be approved if the capability indices for Handicare are greater than the document in the CP & Cpk value greater than <1.33
4. Yellow boxes (Conditional Pass) require conformation of acceptance from R&D, Engineering function or its delegate for CP & Cpk values at <1.00 – 1.33.
5. Reject submission for Red Fail features
6. Features identified as Critical To Quality (CTQ's) shall have monitored Statistical Process Control (SPC) or a suit6able chart to identify runs & tends as evidence of the process stability
7. CTQ's can also be monitored by use of a checking aid that is traceable back to national standards supported by a realistic sampling frequency that is captured in the Control plan and is advised in the Feasibility section.



Cp	1.106	1.155	2.056
Cpk	1.086	0.836	2.007
Result	Conditional Pass	Fail	Pass

Step 8

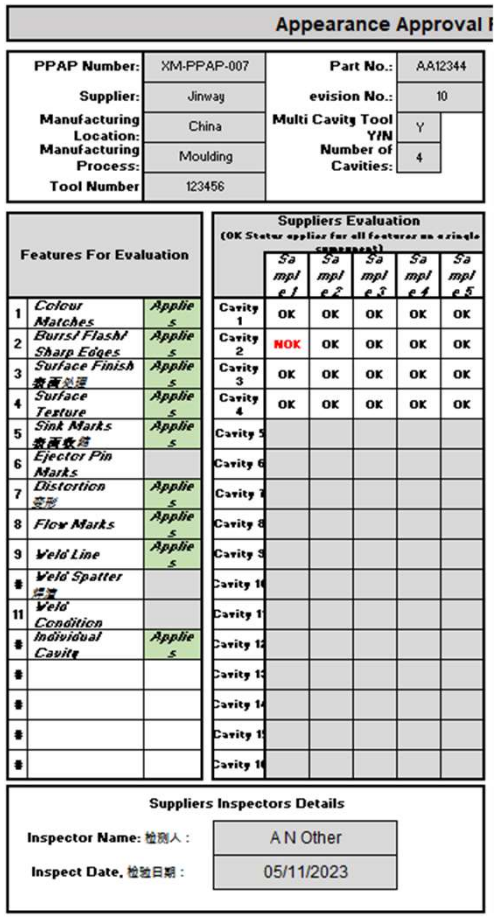
PPAP Element- Appearance Approval Report (AAR)

AAR – Step owner – Supplier, Domestic Quality

Responsibilities:

1. The suppler shall complete the suppliers section of the AAR (Appearance Approval Report) against the mutually agreed finish criteria of production intent tooling.
2. The required sample size is x5off. In the case of moulded parts or castings x5off samples are required from each cavity i.e. x4off impression mould tool will be 4x5 = 20 samples for evaluation.
3. The samples and the report on sent to Handicare for evaluation.
4. Once Handicare accept the AAR report, Purchasing agree a final date from the supplier to supply product with the surface finish treatments i.e. colour, graining, plating, paint etc for evaluation

N.B. This activity takes place PRIOR to adding the texturing to the tooling



Appearance Approval

PPAP Number:	XM-PPAP-007	Part No.:	AA12344
Supplier:	Jinway	evision No.:	10
Manufacturing Location:	China	Multi Cavity Tool Y/N	Y
Manufacturing Process:	Moulding	Number of Cavities:	4
Tool Number	123456		

	Features For Evaluation	
1	Colour Matches	Applies
2	Burrs/ Flash/ Sharp Edges	Applies
3	Surface Finish 表面处理	Applies
4	Surface Texture	Applies
5	Sink Marks 表面收缩	Applies
6	Ejector Pin Marks	
7	Distortion 变形	Applies
8	Flow Marks	Applies
9	Weld Line	Applies
8	Weld Spatter 焊渣	
11	Weld Condition	
8	Individual Cavity	Applies
8		
8		
8		
8		

Suppliers Evaluation
(OK Status applies for all features on a single component)

	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Cavity 1	OK	OK	OK	OK	OK
Cavity 2	NOK	OK	OK	OK	OK
Cavity 3	OK	OK	OK	OK	OK
Cavity 4	OK	OK	OK	OK	OK
Cavity 5					
Cavity 6					
Cavity 7					
Cavity 8					
Cavity 9					
Cavity 10					
Cavity 11					
Cavity 12					
Cavity 13					
Cavity 14					
Cavity 15					
Cavity 16					

Suppliers Inspectors Details

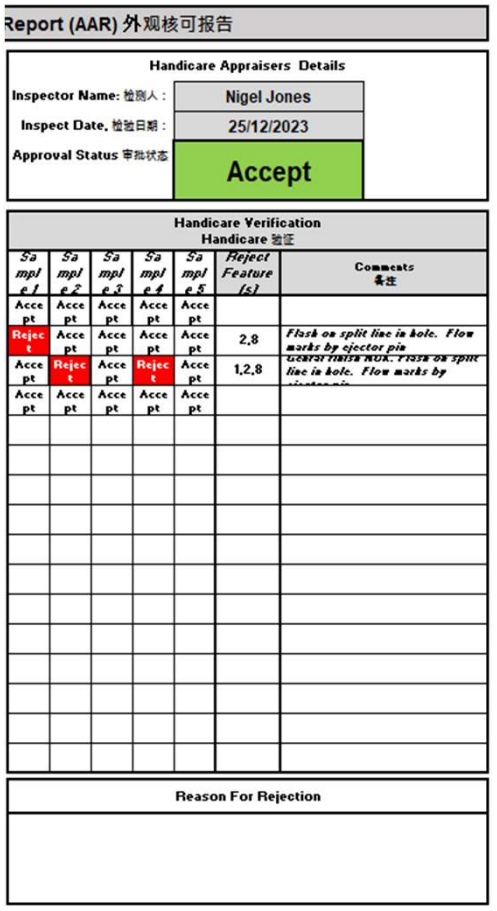
Inspector Name: 检测人：	A N Other
Inspect Date, 检验日期：	05/11/2023

Step 8

PPAP Element- Appearance Approval Report (AAR)

AAR - Handicare PPAP Document Pack Check – DOMESTIC QUALITY & MANUFACTURING

1. That the header information corresponds to the drawing
2. Confirm and agree the suppliers results. Refer to drawing specification, Gold samples, if available, and customer expectations
3. For mouldings check that there is a cavity number
4. Check the x5off samples of each cavity
5. Record on the AAR document, any difference of evaluation on a feature and record the failed feature number in the corresponding sample.
6. If acceptable, to complete the AAR report, Purchasing shall agree a final date to supply product with the surface finish treatments i.e. colour, graining, plating, paint etc for evaluation.
7. Once the surface treatments element has been agreed, Handicare can sign and sentence the AAR document.



Report (AAR) 外观核可报告

Handicare Appraisers Details

Inspector Name: 检测人：	Nigel Jones
Inspect Date. 检验日期：	25/12/2023
Approval Status 审批状态	Accept

Handicare Verification
Handicare 验证

Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Reject Feature (s)	Comments 备注
Accept	Accept	Accept	Accept	Accept		
Reject	Accept	Accept	Accept	Accept	2,8	Flash on split line is hole. Flow marks by ejector pin
Accept	Reject	Accept	Reject	Accept	1,2,8	[illegible] Flash on split line is hole. Flow marks by [illegible]
Accept	Accept	Accept	Accept	Accept		

Reason For Rejection

Step 9

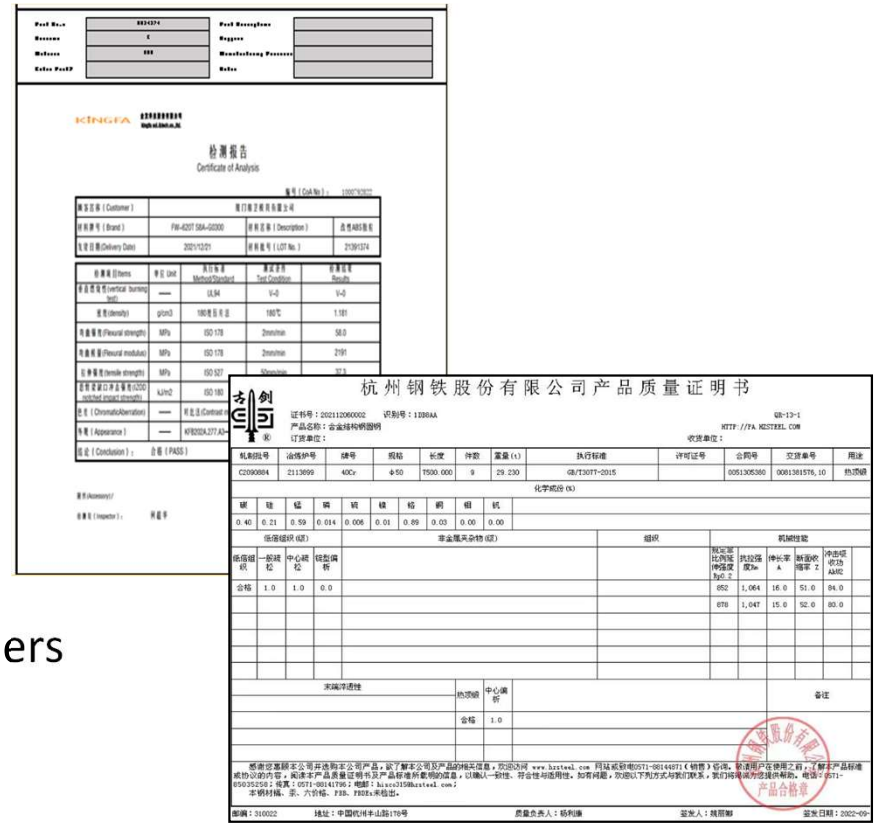
PPAP Element- Material Certification

Material Certification – Step owner – Supplier, Handicare R&D team

Responsibilities:

1. The supplier shall perform test for all parts and product materials when chemical, physical or metallurgical requirements are specified

2. Material certification considered for Inclusion are:
   - Raw material. (Mandatory)
   - Plating/Coating (Mandatory)
   - Heat treatment with test piece results (Mandatory)
   - Plating/Coating endurance testing (If required)
   - Gauge or Measurement equipment calibration providers (If required)



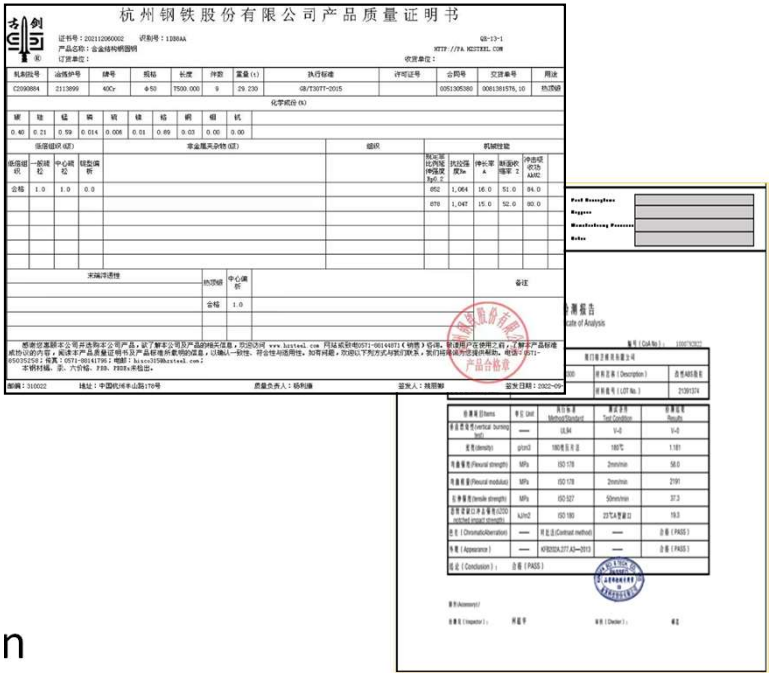
Step 9

PPAP Element- Material Certification

Material Certification - Handicare PPAP Document Pack Check – DOMESTIC QUALITY, R&D, TEST.

1. That the header information corresponds to the drawing

2. Raw Material, Plating and Heat treatment…
   - Traceable back to the submitted samples.
   - Certification results comply to Drawing specification/ requirement
   - Check the criticality box on the header
3. Laboratory or Test service providers to be linked to national standard organisations.
4. Handicare R&D team have confirmed the material certification or test involved and endorsed the PPAP pack template


杭州钢铁股份有限公司产品质量证明书

N.B. The Material Certificate is also part of the FAI submission

Step 10

PPAP Element- Packaging Approval

Packaging Approval – Step owner – Supplier, Supply Chain & Domestic Quality

Responsibilities:

1. The suppler in conjunction with Handicare Supply Chain and Manufacturing team shall develop and agree the delivered part packaging approval
2. Elements to be considered:
   - Images of the supplied part
   - Packaging materials costs
   - Images of the agreed labelling
   - Part marking images internal and external if required
3. Images of the agreed transport packaging if required:
   - Container lorry deliveries
   - Palletisation quantities
   - Individual carton packaging
   - Product protection

Step 10

PPAP Element- Packaging Approval

Packaging Approval - Handicare PPAP Document Pack Check – SUPPLY CHAIN DOMESTIC QUALITY & MANUFACTURING

1. That the header information corresponds to the drawing

2. Images of the piece part reflect the part number in question

3. The footer has both signatures from the supplier and also the Handicare representative and is dated

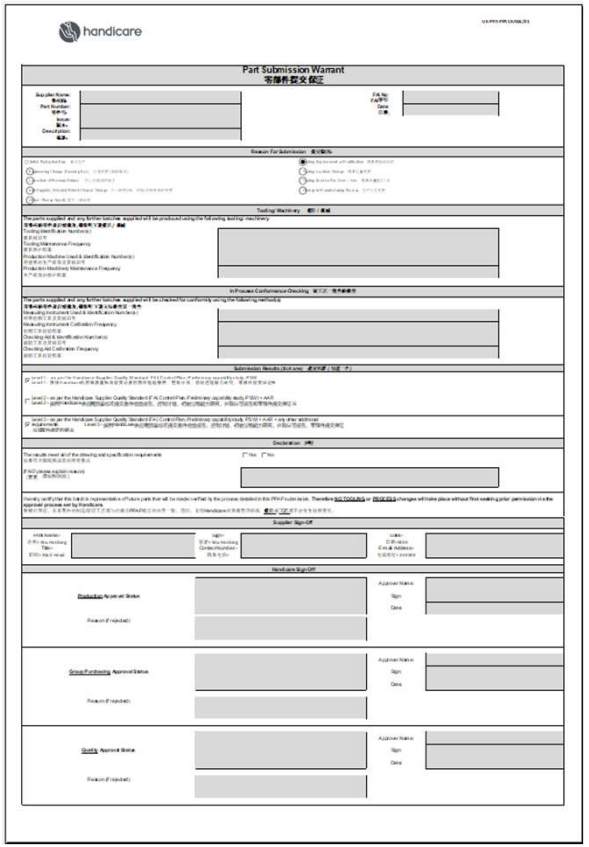
4. All specification regarding the packaging approval to have been agreed and proven in the earlier stages of the development and enquiry

Step 11

PPAP Element- Part Submission Warrant (PSW)

Part Submission Warrant (PSW) - Handicare Document review – Operation Quality

1. The PSW is completed by the Handicare team or there delegate. This is the form that summarises the whole PPAP package and the reason for submission
2. Complete the section that confirms the submitted evidence meets all drawing specification and requirements of the package
3. The PSW document also gives assurance that the submitted parts were manufactured of current manufacturing process meeting the process capability requirements consistently to Handicare
4. If the supplier is not able to meet any of the requirements, the details of the failure and deviation are recorded in the relevant fields of PSW


handicare

Part Submission Warrant

Handicare PPAP Document Pack Check – INTERNAL - DOMESTIC QUALITY

1. That all the PSW sections have been completed signed and dated

2. That there are no rejection comments recorded on the PSW

Only after the full completion of the PSW and the acceptance of the PPAP submission evidence can the supplier begin to produce product and deliver to Handicare facilities

Handicare PPAP submissions Summary

We are re-introducing the PPAP process and moving away from the current components and processes acceptance via the ISIR

The PPAP process needs a disciplined approach by all involved associates within Handicare. The Purchasing Team shall lead and facilitate the process. The Process will require more pre-work before we switch on or make a change. It is necessary so that we improve our product reliability and make the step change to where we want to be in 2025

Requirements

- Team based approach
- Complete the documentation elements
- Improve communication with the supplier
- Provide realistic implementation dates
- Improve engagement with the supplier. Visit there site to understand the processes
- Make decisions based on real data
- Adherence to time schedules by all parties

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Handicare PPAP submissions Summary

STEP	START	ROLES & PRESPONSIBILITIES
1	**Part Approval Request and Requirement (PAR)**	Led by R&D and completed by the Handicare team and with the supplier
2	**Feasibility Review**	Supplier generates and reviews the document with Handicare to ensure full understanding of all product/process expectations on the official drawing
3	Review Process Flow Plan	The Process Flow is completed by the supplier. It identifies all steps and sequences in the fabrication process, including incoming components
4	Review FMEA	Process **Failure Mode and Effect Analysis** (PFMEA) document is a supplier owned and generated document that evaluates and assesses the risk of the steps of the production process and mitigates areas of high risk areas.
5	Review Control Plan	The Supplier generated plan defines the controls required to ensure a consistent part/process. It is reviewed with Handicare
6	Review FAI First Article Submission	Supplier generates a document that is reviewed by Handicare Quality, Manufacturing and R&D before moving to next stage
7	Review Process Capability @ Suppliers Site	Larger samples taken to prove the process is capable and stable before going to full production. Results reviewed by Handicare
8	Review Appearance Approval Report (AAR)	Results reviewed with Handicare Domestic Quality team to ensure customer expectations are fully understood
9	Material Certification	The suppler shall add material certification for traceability purposes and shall perform test to ensure compliance to any stated product materials chemical, physical or metallurgical requirements are specified
10	Confirm Packaging requirement Internally & Externally	All packaging, labelling & handling aspects are considered against Handicare H&S, ergonomic and environmental requirements
11	Review and Sign Part Submission Warrant (PSW)	Completed by the Handicare, Quality, Purchase and Manufacturing teams after agreement of the FAI submission.
12	Checking Aids Additional requirement if requested by Handicare	Supplier generates test reports or output data to support compliance of electrical, electro-mechanical components
13	MSA (Measurement System Analysis) Additional requirement if requested by Handicare	Supplier generates MSA report to demonstrate process repeatability and reproducibility
	FINISH	

Fundamental changes are…

The completion of check lists in the **PAR** and the **Feasibility** documents. Both documents must be signed off by Handicare and the Supplier to acknowledge the necessary requirements against the Approved drawing.

It is important that we have the **Approved drawing** available at this stage so that we can give clear sight to the supplier of the intended design.

During the **Feasibility** review ensure the questions are fully understood and responded too This is the point to flag up potential issues and make them know to Handicare R&D so they can assess or make drawings modifications to make sure the designs can been productionised.

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Handicare PPAP submissions Summary

STEP	START	ROLES & PRESPONSIBILITIES
1	Part Approval Request and Requirement (PAR)	Led by R&D and completed by the Handicare team and with the supplier
2	Feasibility Review	Supplier generates and reviews the document with Handicare to ensure full understanding of all product/process expectations on the official drawing
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4	**Review FMEA**	Process **Failure Mode and Effect Analysis** (PFMEA) document is a supplier owned and generated document that evaluates and assesses the risk of the steps of the production process and mitigates areas of high risk areas.
5	**Review Control Plan**	The Supplier generated plan defines the controls required to ensure a consistent part/process. It is reviewed with Handicare
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	FINISH	

The **Process flow plan** demonstrates the suppliers manufacturing process steps

PFMEA Most likely never issued in the pack. However if it is identified as significant to Handicare then review should be taken a the suppliers premises.

The **Control plan** carries more detail and identifies the controls they have in place to ensure a compliant product. This is what Handicare needs to review preferably at the supplier. Points to note would be sampling sizes and frequencies and important the reaction plan should anything go wrong

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Handicare PPAP submissions Summary

STEP	START	ROLES & PRESPONSIBILITIES
1	Part Approval Request and Requirement (PAR)	Led by R&D and completed by the Handicare team and with the supplier
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5	Review Control Plan	The Supplier generated plan defines the controls required to ensure a consistent part/process. It is reviewed with Handicare
6	**Review FAI First Article Submission**	Supplier generates a document that is reviewed by Handicare Quality, Manufacturing and R&D before moving to next stage
7	**Review Process Capability @ Suppliers Site**	Larger samples taken to prove the process is capable and stable before going to full production. Results reviewed by Handicare
8	Review Appearance Approval Report (AAR)	Results reviewed with Handicare Domestic Quality team to ensure customer expectations are fully understood
9	Material Certification	The suppler shall add material certification for traceability purposes and shall perform test to ensure compliance to any stated product materials chemical, physical or metallurgical requirements are specified
10	Confirm Packaging requirement Internally & Externally	All packaging, labelling & handling aspects are considered against Handicare H&S, ergonomic and environmental requirements
11	Review and Sign Part Submission Warrant (PSW)	Completed by the Handicare, Quality, Purchase and Manufacturing teams after agreement of the FAI submission.
12	Checking Aids Additional requirement if requested by Handicare	Supplier generates test reports or output data to support compliance of electrical, electro-mechanical components
13	MSA (Measurement System Analysis) Additional requirement if requested by Handicare	Supplier generates MSA report to demonstrate process repeatability and reproducibility
	FINISH	

The **FAI First Article Submission** is for the required number of samples identified at the PAR stage. For a mould or casting tool, the sample size applies to each cavity.

The FAI shall consist of the

- FAI FORMS 1, 2 & 3 and the FAI Appendix Sheet
- Against a marked up print or ballooned drawing
- The material certification (Mechanical Properties)

Compliance of the FAI DOES NOT ALLOW START OF PRODUCTION

The Review **Process Capability** at Suppliers site if possible.

- Watch the manufacture off and measurement x30off consecutively manufactured items to prove process the Cp & Cpk capability indices greater <1.33.
- For a mould or casting tool, the sample size applies to each cavity.
- Also applies across all shifts if it is deemed as required

When the Cp & Cpk values are greater <1.33 and the process proven to be capable and stable, can OK to start be issued

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Handicare PPAP submissions Summary

STEP	START	ROLES & PRESPONSIBILITIES
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8	**Review Appearance Approval Report (AAR)**	Results reviewed with Handicare Domestic Quality team to ensure customer expectations are fully understood
9	**Material Certification**	The suppler shall add material certification for traceability purposes and shall perform test to ensure compliance to any stated product materials chemical, physical or metallurgical requirements are specified
10	**Confirm Packaging requirement Internally & Externally**	All packaging, labelling & handling aspects are considered against Handicare H&S, ergonomic and environmental requirements
11	**Review and Sign Part Submission Warrant (PSW)**	Completed by the Handicare, Quality, Purchase and Manufacturing teams after agreement of the FAI submission.
12	Checking Aids Additional requirement if requested by Handicare	Supplier generates test reports or output data to support compliance of electrical, electro-mechanical components
13	MSA (Measurement System Analysis) Additional requirement if requested by Handicare	Supplier generates MSA report to demonstrate process repeatability and reproducibility
	FINISH	

The **Appearance Approval Report (AAR)**
Needs to be reviewed in line with the drawing and R&D especially if surface finishes and textures are visually important.

Material certification
The material certification. Check the Mechanical Properties align to the stated specification.

Confirm Packaging requirement Internally & Externally
Attach images of the agreed packaging and the agreed pricing

Review and Sign Part Submission Warrant (PSW)

Only after the full completion of the PSW and the acceptance of the PPAP submission evidence can the supplier begin to produce product and deliver to Handicare facilities

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Handicare PPAP submissions Summary

STEP	START	ROLES & PRESPONSIBILITIES
1	Part Approval Request and Requirement (PAR)	Led by R&D and completed by the Handicare team and with the supplier
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10	Confirm Packaging requirement Internally & Externally	All packaging, labelling & handling aspects are considered against Handicare H&S, ergonomic and environmental requirements
11	Review and Sign Part Submission Warrant (PSW)	Completed by the Handicare, Quality, Purchase and Manufacturing teams after agreement of the FAI submission.
12	Checking Aids Additional requirement if requested by Handicare	Supplier generates test reports or output data to support compliance of electrical, electro-mechanical components
13	MSA (Measurement System Analysis) Additional requirement if requested by Handicare	Supplier generates MSA report to demonstrate process repeatability and reproducibility
	FINISH	

Although Handicare do not request either the evidence of the **Checking Aids** or of **MSA** as a mandatory item, the documents are still in the PPAP template.

Handicare can highlight these as necessary should the part, process or product demands these tests

These requirements shall be made aware to the supplier at while completing the PAR and the Feasibility sections.

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