1.0 PURPOSE

1.1 This procedure establishes the sequence of events for production part approval process (PPAP), components supplied to all Handicare facilities. This process shall establish confidence in component and the supplier's production processes.

2.0 SCOPE

This procedure applies to all production parts intended for use in a finished device manufactured and assembled in all Handicare facilities. The PPAP package is a formal evidence-based process. Its output is a set of documents providing compliance to specification, performance, and delivery culminating with a formal sign-off by the supplier and approval by the customer (Handicare).

3.0 DEFINITIONS/ABBREVIATIONS

Abbreviation	Description
PAR	Part Approval Request
PPAP	Production Part Approval Process
FAI	First Article Inspection
ISIR	Initial Sample Inspection Report(s)
MSA	Measurement System Analysis
PSW	Part Submission Warrant
FMEA	Failure Mode and Effect Analysis
AAR	Appearance Approval Report
ECN	Engineering Change Notice
RCD	Required Closure Date

4.0 RESPONSIBILITY

R	**Responsible** – who is completing the task
A	**Accountable** – who is making decisions and taking actions on the task(s)
C	**Consulted -** who will be communicated regarding decisions and tasks (2-way communication)
I	**Informed -** who will be updated on decisions and actions (1-way communication)

Table 1: PPAP RACI Matrix (Responsible, Accountable, Consulted & Informed)

TASK	Supplier	R&D	Production	Purchasing	Quality	Supply Chain
Create ECN for the introduction of a new/modified part or Process into serial production.	C	R	I	A	I	I
Create prototype drawing(s)/specification(s) pack for Supplier & Strategic Purchasing Team.	C	R	I	A	I	I
Part Approval Request and Requirement (PAR) document. Handicare team and with the supplier complete and confirm our expectations.	C	A	I	R	I	I
Raise a PO for a minimum of 5 FAI samples for validation purposes	I			R	I	
Feasibility review with Handicare to ensure full understanding of all product/process expectations Send prototype drawing(s)/specification to supplier for evaluation.	C	I	I	R	I	
Flow Plan - The Supplier provides information on the steps required to manufactured item or the process requested in the PAR/ enquiry.	R	I		I	I	
Control plan. The Supplier provides its associated controls to maintain a consistent part/process. It is then reviewed with Handicare for concurrence	R	I		I	I	
The Supplier generates the PFMEA to evaluate the steps taken in the production process and identify high risk areas for failure. It is then reviewed with Handicare for concurrence	R	I		C	I	
Review FAI First Article Inspection Submission. Supplier generates a document that is reviewed by Handicare Quality, Manufacturing and R&D before moving to next stage, process capability.	I	I	I	I	R	
Review Process Capability @ Suppliers Site. Can include Statistical Process Control charts for features identified on drawings and test specification as CTQ's Demonstrate stability and repeatability of the process taken from larger sample sets. Results are reviewed by Handicare if possible, at the supplier's site	A	I	I	R	C	
AAR log and Master Sample log enter details into the appropriate log for tracking	A	C			R	
Review Appearance Approval Report (AAR) Results reviewed with Handicare Domestic Quality team to ensure customer expectations are fully understood	I		I	I	A	I
Confirm the packaging requirement for Internal & External usage. Considered are, quantities, labelling & handling, transportation, ergonomic and environmental impact.	C		I	I	R	C
Review PPAP package and sign off PSW for serial production. Documentation is completed by the Handicare, Quality, Purchase and Manufacturing teams after agreement of the FAI submission.	I	I	C	R	C	I
Review and maintain PPAP log to reflect PPAP status		I	I	R	I	
Tooling schedule. Updated with purchase order number once requirement it has been confirmed by Group Purchasing and Quality	I			R	I	I
*All Completed submissions are stored in **K:\Quality-Sample Reports\PPAP History Folder***		I	I	R	I	I

5.0 PROCESS FLOW

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	

PROCEDURE

5.1 A PPAP submission shall be requested should any of the following events arise.

5.1.1 A new part(s) request.
5.1.2 Changes to the existing product or material that may affect Fit, Form or Function.
5.1.3 Changes to the production process. (Handicare must be Informed)
5.1.4 Interruptions to production lasting longer than 12 months.
5.1.5 Changes to tools or Machines or Machines location (Handicare must be Informed)
5.1.6 Changes to/at sub-suppliers. (Handicare must be Informed)
5.1.7 At the request of the customer (Handicare).

5.2 An ECN shall be raised and linked to support/monitor the PPAP requests.

5.3 Group Purchasing and Quality shall select a supplier from the “approved vendor list” for the required process. Should a new supplier wished to be used, the prospective supplier shall have to meet Handicare selection criteria and allow Handicare to perform their own supplier audit evaluation.

5.4 R&D shall create initial prototype specification/drawing(s) and any necessary models If required, (Ref the PAR), Group Purchasing shall send the prototype specification/drawing(s) pack to the supplier for joint feasibility review completing the feasibility questionnaire.

5.5 A unique PPAP number and document folder shall be created and stored at this location Supplier part approval site Also in this location is PPAP log that will require completion.
Ref Work instruction QOP-G742-05
Prefix "UK"- YEAR-XXXX" for all PPAPs originating at Handicare *Kingswinford*.
Prefix "NL"- YEAR-XXXX" for all PPAPs originating at Handicare *Heerhugowaard*.
Prefix "XM"-YEAR-XXXX" for all PPAPs originating at Handicare *Xiamen*.
Prefix "IT" - YEAR-XXXX" for all PPAPs originating at Handicare *Italy*

5.6 The PPAP doc pack shall be issued to the supplier for PAR and Feasibility review so that the supplier has full understanding of the requirements and can make observations on any issues that they may anticipate.

5.7 If there is an element of development of Tooling, Programming or Process involved the supplier can use the FAI or their own ISIR documentation until the supplier is ready to produce product of a production ready process.

NB. Acceptance of the FAI or ISIR samples does not allow for full production to commence.

5.8 Group Purchasing shall raise a PO (Purchase Order) for a minimum of 5 FAI samples or the agreed samples size for final PPAP submission. Consideration is also given for the run at rate capability study samples that may also be included in the PPAP submission pack.

5.9 Once the supplier has stated that they are supplying product of production intent tooling or processes, the supplier shall complete and submit the full PPAP document pack for review. The submission pack should only consist of the elements that were identified and agreed in the PAR sheet in the PPAP document pack.

5.10 Handicare shall then validate the supplier's full PPAP submission. After the dimensional and documentation evaluation (Ref the PAR) the components shall be submitted for R&D and Handicare Production for Fit, Form and Functional assessment. The AAR (Attribute Appearance Report) and the Packaging Approval document are also assessed for compliance and completion.

5.11 If the submission is successful, The PSW (Part Submission Warrant) is circulated for sign off by Production, Group Purchasing & Quality.

5.12 Only when the PSW has been signed off and the supplier has counter signed and returned the PSW can Supplier start its full production and supply Handicare.

5.13 Temporary Approval is controlled by the Handicare concession request process

Handicare informs the Supplier of the reasons for rejection. The supplier with the guidance of Handicare can supply product or provide services after the submission of and Handicare and approval of a concession request.

Once the application has passed through the concession validation process, product or services can be accepted by Handicare.

The delivery paperwork must state the concession number. This is a temporary action while the supplier identifies solution and implements a corrective action package with a view to re-submit a revised or new PPAP submission pack.

All initial improvements, where possible, must have an increase in surveillance and be supported by data. All improvements made need to be captured and recorded on a revised control plan and be part of a revised PPAP submission

Submission Level Description

The submission level dictates the level of documentation required for a PPAP submission.

The application of each submission level is summarised below. The level of submission and required documentation shall be set out and agreed and documented with supplier at the feasibility of the process.

Refer to Appendix 1 for further details on the elements required for each submission level.

Level	Elements	Application
1	PSW & FAI with product samples and limited supporting data. Refer to the Part Approval Request and Requirement (PAR) for the extent of the supporting documentation required to support submission.	**For components previously approved via Level 3 submission**. Only applies to components with no change to visual attributes, tooling, material, manufacturing equipment or processes, including heat treatment and plating and sub-suppliers.
2	PSW, FAI with product samples and supporting data. Refer to the Part Approval Request and Requirement (PAR) for the extent of the supporting documentation required to support submission. Visual attribute data. Test & performance as defined by Handicare	Can consist of visual attribute data. e.g. colour, plate coating, painting, graining, surface finishes etc... Applies electronic or electro-mechanical adherence to stated Handicare drawing test & performance requirements.
3	PSW, FAI with product samples and other requirements as defined by the customer with full supporting data for review at the supplier and/or Handicare facility Refer to the Part Approval Request and Requirement (PAR) for the extent of the supporting documentation required to support submission.	Can consist of Process Flow plan, Control Plan, Process Capability, AAR (Appearance Report) Packaging Approval, Material certification and review of the suppliers PFMEA and any other requirement as defined by Handicare Applies electronic or electro-mechanical adherence to stated Handicare drawing test & performance requirements.

**Capability study to be conducted to provide process capability for CTQ's, where required*

6.0 RECORDS

6.1 Completed PPAP submission shall be archived with all the associated supporting PPAP records in: **Supplier part approval site**

Appendix 1 – Submission Matrix

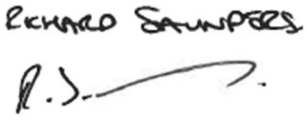
Order	Element	Required Documents	Guidance	Level 1 PPAP Submission	Level 2 PPAP Submission	Level 3 PPAP Submission
0	**Part Approval Request and Requirement (PAR)**	Refer to the PAR	Team based activity to set out Handicare requirement for the PPAP submission. Agreed by the supplier representative.	**REQUIRED**	**REQUIRED**	**REQUIRED**
1	**Supplier Feasibility Commitment**	Feasibility Review	Submission from the supplier acknowledging that the specifications including test and delivery demand and potential uplift can be achieved at mass production level	OPTIONAL As defined by Handicare	**OPTIONAL As defined by Handicare**	**REQUIRED**
3	**Part Drawing**	Approved Handicare Document	All features, dimensional and electrical & electro-mechanical and test requirements clearly identified and understood	**REQUIRED**	**REQUIRED**	**REQUIRED**
4	**Process Flow**	Process Flow Document	Lists all steps required in the manufacture of the part, including measurement / inspections.	NOT REQUIRED	OPTIONAL As defined by Handicare	REQUIRED
5	**Process FMEA**	FMEA Document	Evaluates each step in the production process to identify potential failures.	NOT REQUIRED	OPTIONAL As defined by Handicare	REQUIRED
6	**Control Plan**	Control Plan Document	Identifies the controls in place to maintain a consistent product or process. It is supported by reaction plans in the event of issues arising and is aligned with PFMEA.	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare	REQUIRED
7	FAI First Article Inspection	Supplier completed FAI Documentation and submission	For Mechanical parts - FAI Document dimensional assessment with results, Material Certification, against a Marked-up Print For Electrical or Electro-mechanical items - FAI Document dimensional assessment with Test output results, against a test specification / requirement or Marked-up Print	REQUIRED	REQUIRED	REQUIRED
8	Fit, Form and Functionality	Supplier completed FAI Documentation – Handicare countersignature	Tests conducted by R&D to ensure component or process meets all test and endurance requirements Manufacturing ensure that the component or process does not affect assembly when in production	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare	REQUIRED
9	Process Capability & Test Results	Process Capability Document	Can include Statistical Process Control charts for features identified on drawings and test specification as CTQ's Demonstrate stability and repeatability of the process.	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare	REQUIRED
10	Appearance Approval Report	AAR Document	Appearance approval inspection signed by supplier and customer.	NOT REQUIRED	OPTIONAL As defined by Handicare	REQUIRED
11	Material Certification	Qualified Lab Document / Certificates	Certification of sub-suppliers demonstrating accreditation to ISO 9001.	NOT REQUIRED	OPTIONAL As defined by Handicare	REQUIRED
12	Packaging Approval	Included in Packaging Approval Documentation	Sample production parts sent to customer for approval. A picture is included in the PPAP documentation along with storage location.	NOT REQUIRED	OPTIONAL As defined by Handicare	REQUIRED
13	Sample Product Parts	Physical Item	Supplier and Handicare retain a sample for reference and training	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare
14	PSW Part Submission Warrant	PSW Document	Summarise part information, submission level, drawing numbers and revisions.	REQUIRED	REQUIRED	REQUIRED
15	Checking Aids	Checking Aids Document	Checking aids must include a list of all tools used to verify parts. Part description, tool description and calibration status to be included. Ownership tag must be attached to tooling.	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare
16	Qualified Laboratory	Laboratory Certification linking back to national Standards	This section of the PPAP allows the customer (Handicare) to lists their own specific requirements for the PPAP process.	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare
17	MSA	Gauge R&R studies	Gauge R&R for critical characteristics and confirmation that gauges used to measure characteristics are calibrated.	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare	OPTIONAL As defined by Handicare

REQUIRED Mandatory for this submission Level	**OPTIONAL As defined by Handicare** *Consider, Process changes, Dimensional changes Material Changes or Items with visual attributes e.g. Colour, Plate coating, Painting, Graining, Surface finishes*	**NOT REQUIRED If previously submitted at Level 3 submission**

7.0 Revision History

Revision	Date	Description of the Change	CCR #
01	19th April 2023	New document	101
02	07 Sept 2023	When to issue a PPAP document pack clarified Elements 5.7,5.8,5.9 & 5.10	101

8.0 Approvals

Author (Sign and date)	Quality Manager (Sign and date)
	
Andrew Loffman 07-09- 2023	Richard Saunders 7th Sept 2023