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INSTALLATION TO BE QUALIFIED:

- System qualified:
- Machine type:
- System localization:
- Manufacturer / Editor:
- Supplier identification: *(model, S/N)*
- Installation date:
- Validation plan:

Validation type

- Prospective Validation
- Revalidation
- Concomitant Validation

Origin of validation

- New machine / equipment / computerized system
- Renovation, reparation, machine modification / equipment / computerized system
- Others

Qualification status

- Plan
- Report
- Conform
- Not conform

PLAN APPROVAL				
	WRITER	CHECKER 1	CHECKER 2	APPROVER
Name				
Function				
Date and signature				

B BRAUN	PLAN/REPORT PERFORMANCE QUALIFICATION	BB4PRO870 – V1 du 15/DEC/2021
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Test performer identification			
Name	Function	Signature	Visa

Affected articles				
Designation	SAP reference	Drawing number	Version	Status

Version	Change description
01	Creation
02	XX

OPERATING MODE


Production on the injection mold of three hours series at nominal parameters.

Identify with a « V » the batch number produced.

Sampling:

Control	Batch 1	Batch 2	Batch 3
Process Related Dimension (PRD)	7 shots	7 shots	7 shots
Validated Related Dimension (VRD)	2 shots	2 shots	2 shots
Visual / Physical	Minimum 1536	Minimum 1536	Minimum 1536

Record the batch numbers of the materials used before start-up.

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Defined settings:

In the context of this injection molding process, the parameters having a direct impact on the quality are:

Fixed parameters	Values
Variables parameters	Nominal values

Calibration:

Reference	Title	Status
Type:		Date of conformity:
Serial N°:		Valid for 1 year

5M variation study:

- Material:

The material used can impact the injection parameters. The Flexirene material is being discontinued and is being replaced by Pharmalene. 3 QP runs will be done with Parmalene by changing the batches of material at least once. 1 QP run will be done with the Flexirene in order to demonstrate equivalence.

- Labor / Methods:

The use (starting, monitoring and stopping) of the press is carried out by an operator. The output and packaging of the products are done by operators. There will be at least 3 operator changes during the QP.

- Machine:

The injection parameters have been studied during the OP and the DoE, they will be set at nominal.

- Environment:

The workshop is not air conditioned, the temperature should be read during QP.


As the material is teamed, the hygrometry of the workshop has no impact on the injection. For information, the humidity will be read during the QP.



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Required			Results (To be fulfilled during the report)		
N°	Test description	Acceptance criteria	Results observed	C / NC* Date and Visa	Observation
Visual					
1.1	Integrity, protruding injection point, burrs, color, soiling, black points...			<input type="checkbox"/> C <input type="checkbox"/> NC	
Physical					
1.2	PRD and FRD			<input type="checkbox"/> C <input type="checkbox"/> NC	
Machine characteristic					
1.3	Cycle time Efficiency Scrap			<input type="checkbox"/> C <input type="checkbox"/> NC	

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Documentation				
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1.4	Adjustment sheet			<input type="checkbox"/> C <input type="checkbox"/> NC
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Comments

Place the appendices containing raw data and capabilities at the end of the document, for example. Number and name the appendices, refer to them in the results observed.

* Conform / Not Conform. Add the date and the signature or the VISA of the text performer.