


App: 2 S.O.P: 7-03-02 Valid date: 10/02/2022 Document Status: Released	Appendix Procedure		
	Department: E3D		
Page 1 out of 2	Ver: 5	Subject: App. 2 - E3D CoC for Commercial Sub-Assemblies	

Certificate of Compliance for Commercial Products – Sub-Assemblies

Date: 24/Mar/2025

Customer name and Address: AbbVie Deutschland GmbH & Co. KG, Knollstr. 67061 Ludwigshafen

Elcam's Part #	AbbVie Part #	Specs # and Rev.	Part Name	Batch #	Manufacture Date	Expiry Date	Quantity	PO #	Tailgate samples Quantity
390627	2010291	PS-18-013 Rev. O PS-18-013.2 Rev. I	Front Sub-Assembly AbbVie AAI 0.8 ml	0000897113	15/Mar/2025	15/Mar/2027	31,744	2201689	500

☒ Batch record released

☒ Jabil CoC Issued

☒ Release Tests and Specifications (As applicable):

☒ Visual – all samples inspected and met acceptance criteria.

☒ TB Override/Yield Force – all samples tested and met specifications of less than 2mm travel >80N force is applied.

☒ NS retraction force - all samples tested and met specifications of having a force between 1.0 to 6.0N when the needle shield is pressed.

☒ TB actuation force – all samples tested and met specifications of 3N to 25N.

☒ Plunger Force Capability – all samples tested and met specifications of (mark 1st option for V1/V2 or 2nd for V3):


☒ Break Out (Break loose) force >6N and Gliding force>6N.

☐ Break Out (Break loose) force ≥7.4N and Gliding force≥7.3N.

☒ Residual Deployment Force - all samples tested and met specifications of (mark 1st option for V1/V2 or 2nd for V3):

☒ Min Force>0.5N and Max Force >6N.

☐ Min Force>0N and Max Force >6N.

App: 2 S.O.P: 7-03-02 Valid date: 10/02/2022 Document Status: Released	Appendix Procedure		
	Department: E3D		
Page 2 out of 2	Ver: 5	Subject: App. 2 - E3D CoC for Commercial Sub-Assemblies	

☐ EOD Click Capability- CU hammers must be at a distance of 26.10-27.40mm (for V3 only).

Comments: NA

Elcam Medical certifies that all CoC items meet all requirements of above specification, including visual inspection and dimensional requirements. By shipment of components against the purchase order, Elcam continues to guarantee this Product Numbers (P.N.) as manufactured according to specification requirements and this P.N. conforms to acceptance criteria. Elcam agrees not to make any changes in material, component and/or process which may have impact upon Elcam or not to change manufacturing location without prior written notice of intent to AbbVie.

QA Representative:

Name: Ortal Tsrer

Title: E3D Quality Engineer

Signature: Ortal Tsrer

Date: 27-Mar-2025