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<u>Certificate of Compliance for Commercial Products – Sub-Assemblies</u>

Date: 24/Mar/2025

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

☐ Min Force>0N and Max Force >6N.

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

7 2010291	PS-18-013.2 Rev. I	Assembly AbbVie AAI 0.8 ml	0000897113	15/Mar/2025	15/Mar/2027	31,744	2201689	500
record release	ed							
CoC Issued								
se Tests and Sp	pecifications (As applic	cable):						
⊠ Visual – all sa	amples inspected and	met acceptance cri	teria.					
⊠ TB Override/	Yield Force – all samp	les tested and met	specifications	of less than 2mr	n travel >80N f	orce is applied	l .	
	n force - all samples te	sted and met speci	fications of ha	ving a force betv	veen 1.0 to 6.0	N when the ne	eedle shield is	pressed.
☑ TB actuation force – all samples tested and met specifications of 3N to 25N.								
\square Plunger Force Capability – all samples tested and met specifications of (mark 1 st option for V1/V2 or 2 nd for V3):								
⊠ Break	Out (Break loose) for	ce >6N and Gliding	force>6N.					
☐ Break	Out (Break loose) for	ce ≥7.4N and Glidir	ng force≥7.3N.					
⊠ Residual Dep	loyment Force - all sa	mples tested and m	et specification	ons of (mark 1 st c	ption for V1/V	2 or 2 nd for V3):	
⊠ Min F	orce>0.5N and Max F	orce >6N.						
	CoC Issued ase Tests and Sp Visual – all sa TB Override/ NS retraction TB actuation Plunger Force Break Residual Dep	PS-18-013.2 Rev. I h record released CoC Issued ase Tests and Specifications (As applic Visual − all samples inspected and TB Override/Yield Force − all samp NS retraction force − all samples te TB actuation force − all samples te Plunger Force Capability − all samp Break Out (Break loose) for Residual Deployment Force − all sa	PS-18-013.2 Rev. I AAI 0.8 ml h record released CoC Issued ase Tests and Specifications (As applicable): Visual – all samples inspected and met acceptance crit TB Override/Yield Force – all samples tested and met NS retraction force - all samples tested and met specif TB actuation force – all samples tested and met specif TB actuation force – all samples tested and met specif Plunger Force Capability – all samples tested and met s Break Out (Break loose) force >6N and Gliding Break Out (Break loose) force ≥7.4N and Gliding	h record released CoC Issued ase Tests and Specifications (As applicable): Visual – all samples inspected and met acceptance criteria. TB Override/Yield Force – all samples tested and met specifications of ha NS retraction force – all samples tested and met specifications of ha TB actuation force – all samples tested and met specifications of 3N Plunger Force Capability – all samples tested and met specifications 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	h record released CoC Issued ase 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 □ NS retraction force – all samples tested and met specifications of having a force betw □ 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 opti □ 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 optications)	PS-18-013.2 Rev. I AAI 0.8 ml h record released CoC Issued ase 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 for NS retraction force - all samples tested and met specifications of having a force between 1.0 to 6.0 ☑ 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 ☐ 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)	PS-18-013.2 Rev. I AAI 0.8 ml h record released CoC Issued ase 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 ne ☑ 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)	PS-18-013.2 Rev. I AAI 0.8 ml n record released CoC Issued ase 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 ☑ 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):

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☐ 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 Tsror Title: E3D Quality Engineer Signature: Ortal Tsror Date: 27-Mar-2025