Declaration of Conformity

According to: Medical Device Regulation EU 2017/745

Article 22 (System and Procedure Packs)

Assembler's Name/Registered Trade Name: Takeda Pharmaceuticals U.S.A., Inc.

Assembler's address: 95 Hayden Avenue, Lexington, MA 02421, USA SRN: US-PR-000007896

Product Name: Administration Pack for Veyvondi

Product Code/Category: 5500359, 5500360

Basic UDI-DI Number: 0850025688Veyvondi PackFK

We herewith declare that the following procedure packs meet the provisions of Article 22 of the abovementioned Regulation regarding:

- The mutual compatibility of the medical devices included in the kit
- The relevant Manufacturer information supplied with the medical devices
- The packaging operations was subject to appropriate methods of internal monitoring, verification and validation.

Name / Function: Tara Cox, Head of Device and Combination Product Compliance and Management Representative

Signature:

DocuSigned by:

tara (ox

Signer Name: Tara Cox

Signing Reason: I approve this document Signing Time: 16-Jun-2023 | 12:45:07 BST 044011E2860741A79199166D581F743F Place and Date of Issue: (DD-MMM-YYYY)

Dublin. 16-Jun-2023 | 12:45:15 BST

Certificate Of Completion

Envelope Id: C042267CF40644F0887B3DD1ADC1E76F Status: Completed

Subject: Complete with DocuSign: DECLARATION OF CONFORMITY MDR Regulation EU 2017-745 ARTICLE 22 Procedu...

Department: Pharmaceutical Sciences Quality

Document Type: Design History File

Source Envelope:

Document Pages: 1 Signatures: 1 Envelope Originator: Initials: 0 Certificate Pages: 1 Johann Vallant

AutoNav: Enabled 40 Landsdowne Street Envelopeld Stamping: Enabled Cambridge, MA 02139

Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna johann.vallant@takeda.com IP Address: 147.161.131.95

Record Tracking

Status: Original Holder: Johann Vallant Location: DocuSign

June 16, 2023 | 13:39 johann.vallant@takeda.com

Signer Events	Signature	Timestamp	
Tara Cox		Sent: June 16, 2023 13:43	
tara.cox@takeda.com	tara Cox	Viewed: June 16, 2023 13:44	
Head of Device Compliance and Management	Cinnatura Adoption, Dra colooted Ctula	Signed: June 16, 2023 13:45	
Representative			
Takeda - DocuSign GxP Security Level: Email, Account Authentication (Required)	Signature Adoption: Pre-selected Style Signature ID:		
	044011E2-8607-41A7-9199-166D581F743F		
	Using IP Address: 147.161.237.108		

With Signing Reasons (on each tab): I approve this document

Electronic Record and Signature Disclosure:

Not Offered via DocuSign

In Person Signer Events	Signature	Timestamp	Status:
Editor Delivery Events	Status	Timestamp	: Final
Agent Delivery Events	Status	Timestamp	_
Intermediary Delivery Events	Status	Timestamp	D
Certified Delivery Events	Status	Timestamp	ЭС. #
Carbon Copy Events	Status	Timestamp	Doc. # REC-324884
Witness Events	Signature	Timestamp	1884
Notary Events	Signature	Timestamp	
Envelope Summary Events	Status	Timestamps	Final
Envelope Sent Certified Delivered Signing Complete Completed	Hashed/Encrypted Security Checked Security Checked Security Checked	June 16, 2023 13:43 June 16, 2023 13:44 June 16, 2023 13:45 June 16, 2023 13:45	Final Date: 19 Jun 2023
Payment Events	Status	Timestamps	5

With Signing Authentication via DocuSign password

Document Approvals Approved Date:

Task: QA Verification Verdict: Passed True Copy Verification Check

Scott Evans, (scott.evans@takeda.com) Quality 19-Jun-2023 13:00:14 GMT+0000