

CERTIFICATE OF APPROVAL OF VARIATION(S) FOR A REGISTERED PHARMACEUTICAL PRODUCT

Application No. : 68035

Registration No.	18-4499
Product Name	Tremfya 100 mg / ml Prefilled Syringe
Generic & Strength	Guselkumab
Pharmaceutical Form	Solution for injection
Shelf Life	24 Months
Pack Size	1 Pre-filled syringe (1ml)
Packaging Materials	pre-filled syringe
MAH Company	Janssen Cilag International N.V. Address: Turnhoutseweg 30, B-2340 Beerse, Belgium
Agent	UNIPHARM TRADING LLC

Minor Variation Details:

Variation Type	Description
45.a.1 Addition of new indication or modified indication and consequential changes including new dose instructions: New dose regimen with no change in indications	PIL version July 2022 (see enclosed comparison table)  PIL version May 2025 (see enclosed comparison table)
40. Change in outer pack & label (artwork, dimension, logo, etc..) replacement or deletion of measuring administration devices on integrated part of primary pack	Current outer box (see enclosed comparison table)  Proposed outer box (see enclosed comparison table)

NOTES/CONDITIONS:	Variation 47 of GCC guideline 6.2: Addition of the electronic patient leaflet ( statement and barcode) to outer package artwork ( Mock-up) Current outer box does not have Nashratech QR code Proposed: NashraTech Project Addition of QR Code on the outer boxes for ePIL
IMPLEMENTATION DATE:	26/02/2026