Surgiflo Haemostatic Matrix Kit

Procedural steps taken and scientific information after the initial consultation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after initial consultation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	Outcome:	03/08/2026			To submit a 2nd step notification procedure.

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000357505	This was an application for a group of variations. - Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA - Accepted - Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB - Accepted				Change to an in-house reference standard/preparation for a biological active substance.
Variation type II / EMA/VR/0000287744	Outcome: This was an application for a group of variations. - Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA - Accepted - Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB - Accepted - Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II - Accepted - Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB - Accepted - Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA - Accepted - Minor changes to an ancillary medicinal substance - Post consultation procedure	09/10/2025			001. AMS.IA: To replace the non-significant parameters in the specifications of the finished product water for injection; 002. AMS.IB: To add an alternative pre-filled syringe containing sterile water for injection to the medical device Surgiflo Haemostatic Matrix Kit; 003. AMS.II: Change in the immediate packaging of the sterile finished product pre-filled syringe containing sterile water for injection; 004. AMS.IB: To an alternative site responsible for manufacturing of the finished product pre-filled syringe containing sterile water for injection; 005. AMS.IA: To add an alternative site responsible for quality control testing and batch release of the finished product pre-filled syringe containing sterile water for injection; 006. AMS.IA: To submit 2nd step notification procedures for PMF.

	equivalent to IA - Accepted - - Accepted				