Floseal Hemostatic Matrix (Floseal VH S/D)

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 /	- Minor changes to an ancillary medicinal	07/07/2025	N/A		Update of the Adventitious Agents Safety Evaluation

[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/0000273332	substance - Post consultation procedure equivalent to IB - Accepted				for Human Albumin
Variation type IA_IN / EMA/VR/0000279019	- Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA - Accepted	01/07/2025	N/A		To submit a 2nd step notification procedure
Variation type IB / EMA/VR/0000265401	This was an application for a group of variations. - 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 IB - Accepted	26/05/2025	N/A		Minor changes to an approved test procedure for the active substance. Minor changes to an approved test procedure for the finished product.