FertiPro N.V. HSA-containing ART media

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification[1] issued on	Summary
IA/0004	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	19/12/2022	To submit a 2nd step notification procedure.
IA/0003	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	03/02/2021	To update the address of the manufacturer of Human Albumin Solution, Octapharma AB. To submit a 2nd step notification procedure.
IA/0002	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	15/12/2020	To change the Notified Body from DEKRA Certification B.V. (Utrechtseweg 310, P.O. Box 5185, 6802 ED Arnhem, the Netherlands) to BSI Group The Netherlands B.V. (Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands).

[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.

			To reconfirm the Scientific opinion granted under MDD (93/42/EEC) for the purpose of certification under MDR (MDR/2017/745).
II/0001	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	23/01/2014	To add an alternative Human Albumin Solution 25% (marketed under the trade name of Albunorm 25%) manufactured by Octapharma GmbH to the previously assessed Human Albumin Solution 25% manufactured by Talecris Biotherapeutics (DE).