



CooperSurgical Inc ART Media

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification ¹ issued on	Summary
IA/0010	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	25/08/2023	To update the legal manufacturer to CooperSurgical, Inc. and to reconfirm the Scientific Opinion granted under MDD (93/42/EEC) for the purpose of certification under MDR (MDR/2017/745). To remove a manufacturing site.
IA/0009	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	21/02/2023	To submit a 2nd step notification procedure.
IA/0008	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	09/09/2022	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.



IA/0007	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	16/10/2020	To change the Notified Body from BSI Group (Kitemark Court, Davy avenue, Knowlhill, Milton Keynes, MK5 8 PP, United Kingdom) to BSI Group The Netherlands B.V. (Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands). To submit a 2nd step notification procedure.
II/0006/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	02/04/2020	To adjust the manufacturing process of SAGE IVF media: dilution step of the Human Serum Albumin (HAS). To add Instituto Grifols, S.A. as new manufacturer of 20% Human Serum Albumin (HAS).
IB/0005	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	09/04/2018	To add two new media, SAGE Vitrification Kit (ART-8026) and SAGE Vitrification Warming Kit (ART-8031), for Assisted Reproduction Technologies to the CooperSurgical, Inc. ART media
IB/0004	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	24/11/2015	To introduce an additional medium 10% PVP Ready to use Solution (ART – 4006-A).
IB/0002	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	15/06/2015	To replace the manufacturer of the medical device Sage IVF, Inc. (a CooperSurgical, Inc. company) 1979 E. Locust Street, Pasadena CA, 91107 USA with Origio a/s (a CooperSurgical, Inc. company), Knardrupvej 2, 2760, Malov, Denmark. The applicant/manufacturer of the medical device remains the same legal entity.
IA/0001	B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients	16/09/2011	To include two additional IVF media Quinn's Advantage Fertilization (HTF) Medium, 50 ml and Quinn's Advantage Fertilization (HTF) Medium, 100ml.