



CooperSurgical Inc ART Media

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification ¹ issued on	Summary
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.
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.

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.



II/0006/G	<p>This was an application for a group of variations.</p> <p>Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB</p> <p>Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II</p>	02/04/2020	<p>To adjust the manufacturing process of SAGE IVF media: dilution step of the Human Serum Albumin (HAS).</p> <p>To add Instituto Grifols, S.A. as new manufacturer of 20% Human Serum Albumin (HAS).</p>
IB/0005	<p>Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB</p>	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	<p>Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB</p>	24/11/2015	To introduce an additional medium 10% PVP Ready to use Solution (ART – 4006-A).
IB/0002	<p>Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB</p>	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	<p>B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients</p> <p>- Any minor adjustment of the quantitative composition of the finished product with respect to excipients</p>	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.