



12 November 2024
EMA/529198/2024 Rev.2
Human Medicines Evaluation Division

Irvine Scientific Reproductive Media

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification ¹ issued on	Summary
IB/0008	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	12/11/2024	To reconfirm the Scientific opinion granted under MDD (93/42/EEC) for the purpose of certification under MDR (MDR/2017/745), and to submit a 2nd step notification procedure.
IB/0006	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	28/03/2019	To add two new solutions to the range of IVF media: Vit Kit - Freeze NX (Catalog #90188) and Vit Kit - Warm NX (Catalog #90183). There is no change in the Human Serum Albumin solution manufactured by Octapharma.
IB/0005	Minor changes to an ancillary medicinal substance -	30/01/2019	To add two new solutions to the range of IVF media: Continuous Single Culture®-NX Complete

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.



	Post consultation procedure equivalent to IB		(CSCM-NXC) (Catalog #90168) and Arctic™ Sperm Cryopreservation Medium (Catalog #90170).
IB/0004	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	21/07/2015	To add two new solutions to the range of IVF media: Multipurpose Handling Medium (MHM) (Catalog #90163) and Continuous Single Culture (CSCM) (Catalog #90164).
IB/0003	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	13/09/2013	To add three additional new media solutions to the range of IVF media: Multipurpose Handling Medium TM Complete (catalogue # 90166), Embryo Biopsy Medium (Catalogue #90103) and Hyaluronidase Solution (Catalogue #90101).
IB/0002	B.II.z - Quality change - Finished product - Other variation	23/10/2012	To add a new medium solution: Continuous Single Culture Complete (CSC-C) (Cat. N. 90165).
II/0001	Follow-up consultation on an ancillary medicinal substance due to an amendment to the documentation	19/11/2009	To add an alternative Human Albumin Solution 25% (marketed under the trade name of Alburnorm 25%) manufactured by Octapharma GmbH to the previously assessed Human Albumin Solution 25% manufactured by Talecris Biotherapeutics (DE).