



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/502063/2023 Rev. 1

Origio A.R.T. Media

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification ¹ issued on	Summary
IA/0001	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	08/11/2023	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).

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.

