Medicines & Healthcare products Regulatory Agency

MHRA

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MR. J-F De Luis
CIS BIO-INTERNATIONAL
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F-91192
FRANCE

15/12/2020

Dear MR. De Luis,

APPROVAL

Our Reference:	PL 11876/0009 - 0037
Your Reference:	DOS-CTD-142/016
Product:	Pulmocis kit for preparation of technetium human albumin macroaggregates injection
Type of Procedure:	National
Submission Type:	Variation
Submission Category:	Type IB
Submission Complexity:	Standard
EU Procedure Number (if applicable):	
Reason:	To update the data relating to plasma for fractionation of the Pulmocis kit.

The Licensing Authority agrees to the above submission(s), including any replacement and amendment pages of the original that were provided with your written request.

The approval date is 15/12/2020.

Please retain this letter with the formal documents relating to the Marketing Authorisation/Registration as evidence of approval.

All Marketing Authorisations/Registrations are subject to standard provisions contained in current medicines regulations, full details of which are published on the MHRA website:
http://medicines.mhra.gov.uk/ourwork/licensingmeds/licensingmeds.htm

Yours sincerely,

MHRA