Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

NATIONAL CONTROL AUTHORITY RELEASE CERTIFICATE FOR IMMUNOLOGICAL PRODUCTS

Finished Product

Examined in accordance with regulations 60A and 60B of the Human Medicines Regulations 2012

NIBSC Release Certificate Number:	
Trade Name:	
International non-proprietary name / Pharmacopoeia Name / Common Name:	
Batch number appearing on package and other identification numbers associated with this batch:	
Type of container:	
Total number of containers in this batch:	
Nominal dose per container:	
Date of start of period of validity:	
Date of expiry:	
Marketing Authorisation Number: Issued by:	MHRA, United Kingdom
Name and address of Manufacturer:	
Name and address of Marketing Authorisation Holder if different	

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard.

This examination is based on either:

- the relevant control testing guideline for this product, or, in the absence of this,
- the appropriate control laboratory tests as indicated in the marketing authorisation application and/or the review of the manufacturer's protocol.

This batch is compliant with the approved specifications laid down in the above marketing authorisation.

Name:

Function of Signatory: Head of Division

Date of Issue:

Signed:

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory