Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

WHO Certificate for the Batch Release of Immunological Products

Our reference:

Trade name:	
International non-proprietary Name / Common name:	
Batch numbers appearing on package and other identification numbers associated with this batch:	
Type of container used:	
Total number of containers or lot size:	
Number of doses per container:	
Date of start of period of validity (e.g. manufacturing date):	
Date of expiry (DD/MM/YYYY):	
Storage conditions	
Diluent lot number(s) (if applicable):	
Diluent expiry date(s):	
Marketing authorisation number (member state) issued by :	
Name and address of manufacturer:	
Site(s) of manufacturing:	
Name and address of marketing authorisation holder if different:	

- The following lot(s) of **YYYY** vaccine produced by **XXXX**[1] whose numbers appear on the labels of the final evaluated containers, complies with the relevant marketing authorization, the national specifications and provisions for the release of biological products[2] and Part A[3] of the WHO Recommendations to assure the quality, safety and efficacy of the concerned vaccines (**ZZZZ**)[4] and with corresponding WHO recommendations for each of the vaccine's individual components, as well as with WHO good manufacturing practices: main principles for pharmaceutical products[5]; Good manufacturing practices for biological products[6]; and Guidelines for independent lot release of vaccines by regulatory authorities[7].

-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. The release decision is based on the elements described in paragraph 7.3 of the Lot Release guideline[7].

1: Name of manufacturer.
2 If any national requirements have not been met, specify which one(s) and indicate why the release of the lot(s) has nevertheless been authorized by the NRA.
3: With the exception of provisions on distribution and shipping, which the NRA may not be in a position to assess.
4: **ZZZZ**
5: WHO Technical Report Series, No. 986, Annex 2.
6: WHO Technical Report Series, No. 999, Annex 2.
7: WHO Technical Report Series, No. 978, Annex 2.
8: Evaluation of the product-specific summary protocol and independent OMCL testing

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released[8].

Signed on behalf:

XXXX
Section

Date of issue: **DD.MM.YYYY**

Certificate number: **XXXXX/XX**

This document was issued electronically and is therefore valid without signature.