

Date of issuance: 23 May 2024

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 002/2024

The following lot of CERVARIX SUSPENSION FOR INJECTION (MAL20071726ARZ) produced by GLAXOSMITHKLINE BIOLOGICALS S.A, RIXENSART, BELGIUM, whose numbers appear on the labels of the final containers, **DOES NOT MEET** the requirements as below:

- National requirement on Good Distribution Practice for Cold Chain
- National requirement on Lot Summary Protocol Evaluation
- National requirement on Physical Appearance Testing
- Requirements for recombinant human papillomavirus virus-like particle vaccines, WHO Technical Report Series, No.999, 2016, Annex 4

Product Registration Holder: GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.

Lot no: AHPVA455AE


Expiry date: 31 July 2027

No. of doses: 9,900

No. of doses per container: 1

Signature:

Name of authorized person:


NORHALIZA BINTI A HALIM
Senior Director of Pharmaceutical Services
Ministry of Health Malaysia