

Date of issuance: 12 May 2017

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 0001/2017

The following lot of GARDASIL SUSPENSION FOR INJECTION (MAL20061596ARZ) produced by Merck Sharp & Dohme Corp, West Point, USA, 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

Recommendations to assure the quality, safety and efficacy of recombinant Human Papillomavirus Virus-like particle vaccines, WHO Technical Report Series. No. 999. 2016. Annex 4

Submission of evidence of product destroy is compulsory before 12 September 2017

Lot No	Expiry date	No. of containers	No. of doses per container
N009440	31 October 2019	4,800	1

Signature:

Name of authorized person:

SITI AIDA BINTI ABDULLAH
Deputy Director for Pharmacy Regulatory
National Pharmaceutical Regulatory Division
Ministry of Health Malaysia

Signature:

12 May 2017