

Status	Effective	Effective Date	-	Version	4.0	Doc Name	FORM-56937
Title	FORM: Template Manueel Certificaat Nimenrix						
Doc Alias	NVT		Site Code / Department		Puu / Batch Dispositioning		

	Certificate of Compliance Manufacturer's Declaration	Page [1 of 1]
	PFIZER MANUFACTURING BELGIUM NV RIJKSWEG 12 B-2870 PUURS (BELGIUM) TEL: +32 (0)3 890.92.11 FAX: +32 (0)3 889.65.32	

Product Name: NIMENRIX SFDPO 1X0.5ML GVL+SYR

Strength/Potency: After reconstitution of the powder with the solvent (diluent), 1 dose (0.5 mL) contains -

- 5 micrograms of *Neisseria meningitidis* group A polysaccharide¹
 - 5 micrograms of *Neisseria meningitidis* group C polysaccharide¹
 - 5 micrograms of *Neisseria meningitidis* group W₁₃₅ polysaccharide¹
 - 5 micrograms of *Neisseria meningitidis* group Y polysaccharide¹
- ¹ conjugated to tetanus toxoid carrier protein

Batch Number: AL8657

SF Batch Number: AMECA090B

Diluent Batch Number(s): AD02A046A

Date of Manufacture: 03/2018

Expiration Date: 02/2022

Disposition Date: 13/03/2019

THE ABOVE PRODUCT INCLUDING THE ACTIVE SUBSTANCE HAS BEEN MANUFACTURED AND TESTED IN ACCORDANCE WITH MANUFACTURING INSTRUCTIONS, TESTING STANDARDS AND CGMP. IT CONFORMS WITH SPECIFICATIONS AND IS SUITABLE FOR RELEASE UNDER THE CONDITIONS OF THE FOLLOWING LICENSES: EU/1/12/767/001-007 AS APPLICABLE.

THIS IS ALSO TO CERTIFY THAT, WHERE APPLICABLE, ANY MATERIALS DERIVED FROM RUMINANTS (BOVINE, OVINE, CAPRINE) USED IN THE MANUFACTURE AND/OR FORMULATION OF THE BATCH OF PRODUCT SPECIFIED ABOVE FULFILL THE PRESCRIPTIONS DEFINED IN COMMISSION DIRECTIVE EMA/410/01 AND HAVE THEREFORE BEEN DEMONSTRATED TO BE IN ACCORDANCE WITH THE CURRENT CPMP "NOTE FOR GUIDANCE ON MINIMIZING THE RISK OF TRANSMITTING ANIMAL SPONGIFORM ENCEPHALOPATHY AGENTS VIA MEDICINAL PRODUCTS", THROUGH THE PH. EUR. CERTIFICATION PROCEDURE.

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Name: *Dejaeghe Ey*

Signature:

[Signature]

Date: *14/03/2019*

Destination country/countries of the batch: BELGIUM

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.