MERIAL

EUROPEAN BATCH RELEASE PROTOCOL

PRODUCT: **CRYOMAREX RISPENS + HVT**

MEMBER STATE SPECIFIC INFORMATION

Batch number of finished product: 163A21

Release date of finished product: 01-Feb-2017

Marketing authorisation number: 2205/1/07 MgSzH ATI

Issued by: HUNGARY

Target species: CHICKENS

Total number of containers in this batch: 14560

Number of containers the release is applied for: 14560

Number of doses per container: Ampoule of 1000 doses

Number of samples for the competent authority: Available upon request

Date of expiry: 09/2019

Name and Address of Marketing Authorisation Holder:

MERIAL
29, avenue Tony Garnier
69007 LYON
France

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SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Trade name: CRYOMAREX RISPENS + HVT

INN / PE name / common name of product: Marek's disease (live) vaccine

Batch number of:

Finished product:	Final batch:	Final bulk:
163A21	16CRH3A21	16CRH3A20

Pharmaceutical form of finished product: Frozen suspension and solvent for suspension for injection

Type of final container: Ampoule of glass

Date of start of period of validity: 13-Oct-2016

Storage: Liquid nitrogen

Name and address of manufacturer:
MERIAL
Lentilly
1, chemin de Cruzols
69210 Lentilly
FRANCE

Name and address of the batch release site :
MERIAL
Lyon Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
FRANCE

CERTIFICATION BY THE MANUFACTURER

I herewith certify that batch CRYOMAREX RISPENS + HVT n° 163A21 was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirement and that all measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended by Directive 2004/28/EC.

Date: 02-Feb-2017

Signature

Dr Véronique SARRÈRE
Substitute Deputy Qualified Person
Merial Lyon