

HUNGARY  
22017031



UNE SOCIÉTÉ SANOFI

Site de Lyon - Porte-des-Alpes

Rue de l'Aviation

69800 Saint-Priest - France

Tel. +33 (0) 4 72 72 30 00

Fax +33 (0) 4 72 72 34 91

## EUROPEAN BATCH RELEASE PROTOCOL

PRODUCT: **CRYOMAREX RISPENS + HVT**

### MEMBER STATE SPECIFIC INFORMATION

**Batch number of finished product:** 43E005

**Release date of finished product:** 16-Dec-2014

**Marketing authorisation number:** 2205/1/07 MgSzH ATI

**Issued by:** HUNGARY

**Target species:** CHICKENS

**Total number of containers in this batch:** 14319

**Number of containers the release is applied for:** 14319

**Number of doses per container:** Ampoule of 1000 doses

**Number of samples for the competent authority:** Available upon request

**Date of expiry:** 09/2017

**Name and Address of Marketing Authorisation Holder:**

MERIAL  
29, avenue Tony Garnier  
69007 LYON  
France

HUNGARY  
22017031



Site de Lyon-Porte-des-Alpes  
Rue de l'Aviation  
69800 Saint-Priest - France  
Tel: +33 (0) 4 72 72 30 00  
Fax: +33 (0) 4 72 72 34 91

## 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:
43E005	4CRH3E005	4CRH0E005

**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:** 26-Sep-2014

**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 :**

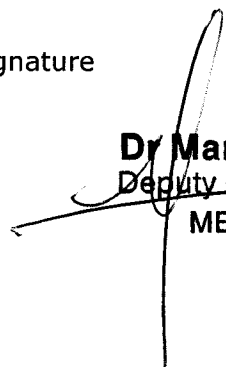
MERIAL  
Lyon Porte des Alpes  
Rue de l'Aviation  
69800 Saint Priest  
FRANCE

### CERTIFICATION BY THE MANUFACTURER

I herewith certify that batch CRYOMAREX RISPENS + HVT n° 43E005 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: 23-Jan-2015

Signature

  
**Dr Marc TEICHNER**  
Deputy Qualified Person  
MERIAL LYON