

HUNGARY  
22018374



Site de Lyon-Porte-des-Alpes  
Rue de l'Aviation  
69800 Saint-Priest - France  
Tel. +33 (0) 4 72 72 30 00  
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## EUROPEAN BATCH RELEASE PROTOCOL

PRODUCT: **CIRCOVAC**

### MEMBER STATE SPECIFIC INFORMATION

**Batch number of finished product:** L418714

**Release date of finished product:** 27-Feb-2015

**Marketing authorisation number:** EU/2/07/075/003

**Issued by:** HUNGARY

**Target species:** PIGS

**Total number of containers in this batch:** 727

**Number of containers the release is applied for:** 727

**Number of doses per container:** Bottle of 25 doses

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

**Date of expiry:** 17-Nov-2016

**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:** CIRCOVAC

**INN / PE name / common name of product:** Swine Circovirus (inactivated, adjuvanted) vaccine

**Batch number of:**

Finished product:	Final batch:	Final bulk:
L418714	4CVC20451	4CVC20450
L418714	4TS60441	4TS60440

**Pharmaceutical form of finished product:** Suspension and o/w emulsion for o/w emulsion for injection

**Type of final container:** Bottle of glass

**Date of start of period of validity:** 17-Nov-2014

**Storage:** 2°C-8°C

**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

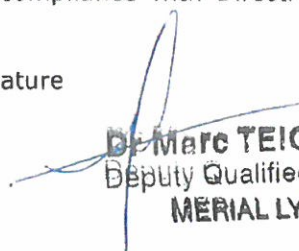
**QP Comment:** Tech 10011 : This result complies with the product specifications according to QA retest procedure.

### CERTIFICATION BY THE MANUFACTURER

I herewith certify that batch CIRCOVAC n° L418714 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: 26-May-2015

Signature

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

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