Intervet International bv
P.O. Box 31
5830 AA Boxmeer
The Netherlands
T +31 485 58 7600
F +31 485 56 8111
msd-animal-health.com

MSD Animal Health

Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A099A03*

MEMBER STATE SPECIFIC INFORMATION

Member state: **HUNGARY**

Antigen containing component:

Trade name:	**Bovilis BVD**
Marketing authorisation number:	
Target species:	**Cattle**
Total number of containers in this batch:	**30 252**
Number of containers the release is applied for:	**30 252**
Number of doses per container:	**10**
Number of samples for the competent authority:	-
Date of expiry:	**Jul-2015**
Name and address of Marketing Authorisation Holder:	**Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer THE NETHERLANDS, represented by the local company**

10-Oct-2014/mw
1103428734/10

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Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A099A03*

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	**Bovine viral diarrhoea vaccine (inactivated).**
Batch number of finished product:	**A099A03**
Batch number of final bulk:	**A099**
Pharmaceutical form of finished product:	**Suspension for injection**
Type of final container:	**PET bottles**
Date of start of period of validity:	**30-Jan-2014**
Storage temperature:	**2-8° C**
Name and address of manufacturer:	**Intervet International B.V.** **Wim de Körverstraat 35** **5831 AN BOXMEER** **NEDERLAND**
Name and address of the batch release site:	**Intervet International B.V.** **Wim de Körverstraat 35** **5831 AN BOXMEER** **NEDERLAND**

CERTIFICATION BY THE MANUFACTURER

I herewith certify that concerned batch 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.

Name: P.G. Mooren
Function: Qualified Person
Date: 20 OCT 2014
Signature:

Trade register No: 16028015

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Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A099A03*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Sterility (F09)
05-Feb-2014	26-Feb-2014	Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1. Result: No growth Threshold: No growth Conclusion: Passed
07-Feb-2014	19-Feb-2014	**Inactivation (F03)** Result: Inactivated Threshold: Inactivated Conclusion: Passed
		Potency using mice (F11)
30-Jan-2014	20-Mar-2014	Result: Conform Threshold: Conform Conclusion: Passed
		Potency BVDV (VN)
		Single result: 8 / 8 / 10 / 5 / 7 / 7 Log 2 Average: 7.5 Log 2 Threshold: >= 5.6 Log 2 Conclusion: Passed
		Methyl parahydroxybenzoate (F08)
02-Apr-2014	02-Apr-2014	Result: 1.4 mg/mL Threshold: 1.2 - 1.8 mg/mL Conclusion: Passed
		Aluminium (F08)
10-Feb-2014	10-Feb-2014	Tested according to Ph. Eur. 2.5.13 Result: 3.7 mg/mL Threshold: 3.0 - 4.5 mg/mL Conclusion: Passed
		pH (F08)
28-Feb-2014	28-Feb-2014	Tested according to Ph. Eur. 2.2.3 Result: 7.4 Threshold: 7.0 - 7.8 Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A099A03*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Visual appearance (F08)
23-Jan-2014	23-Jan-2014	Result: Conform Threshold: Pink turbid suspension Conclusion: Passed
		Final inspection (F13)
23-Jan-2014	23-Jan-2014	Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A099A03*

PRODUCTION INFORMATION

Component	Batch	Site(s) of manufacturing
Antigen	See composition table	Intervet, Boxmeer, the Netherlands
Antigen	See composition table	Intervet, Salamanca, Spain
Bulk vaccin	see blending	Intervet, Boxmeer, the Netherlands
Filled product	see filling	Intervet, Boxmeer, the Netherlands

STARTING MATERIALS:

Virus seed lots:
Master seed material: **BVD virus strain C86**
MS-batch number: **F22.4.91**
Date of last testing: **25-AUG-1994**

Working seed material: **BVD virus strain C86**
WS-batch number: **27D09**
Date of last testing: **10-Jul-2009**

Permanent cell line:
Master cell seed: **JCK cell line**
MCS-batch number: **JCK 56° MCS/3**
Date of last testing: **11-MAY-1999**

INTERMEDIATE STAGES OF PRODUCTION

PRODUCTION OF BVD COMPONENT:

Production step	Start	End	Volume
Batch BBVD3101			
Seed:	31-May-2013	31-May-2013	0.0142 ml/rb
Harvest:	06-Jun-2013	06-Jun-2013	470 kg
Inactivation:	06-Jun-2013	06-Jun-2013	499 kg
Batch SBVD13001			
Seed:	28-May-2013	28-May-2013	0.03 ml/rb
Harvest:	03-Jun-2013	03-Jun-2013	690.40 kg
Inactivation:	03-Jun-2013	03-Jun-2013	704.50 kg

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A099**
Start date: **15-Jan-2014**
End date: **16-Jan-2014**
Total volume: **904.9 kg**

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Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A099A03*

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	SBVD13001 BBVD3101	38.90 kg	4.30 %
Adjuvant	0000269573 0000284049 0000269574	454.30 kg	50.20 %
Excipient	0000257120 0000219280 BMGM318601 BMGM312071 0000264744	410.37 kg	45.35 %
Preservative	0000198409	1.36 kg	0.15 %

FILLING

Batch number of final bulk: **A099**
Final batch number: **A099A**
Start date: **20-Jan-2014**
End date: **20-Jan-2014**
Filled containers: **30 252**
Volume filled: **20 ml**

IN PROCESS CONTROLS

In process controls BVD antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch BBVD3101					
Antigen content	30-Jul-2013	30-Jul-2013	500 EU/ml	n.a.	Passed
Inactivation	09-Aug-2013	21-Aug-2013	Inactivated	Inactivated	Passed
Sterility	14-Jun-2013	05-Jul-2013	No growth	No growth	Passed
Batch SBVD13001					
Antigen content	30-Jul-2013	30-Jul-2013	770 EU/ml	n.a.	Passed
Inactivation	07-Jun-2013	19-Jun-2013	Inactivated	Inactivated	Passed
Sterility	07-Jun-2013	28-Jun-2013	No growth	No growth	Passed

In process controls final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume	20-Jan-2014	20-Jan-2014	21 ml	>= 21 ml	Passed

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Model for manufacturers of a MARKETING INFORMATION FORM

Notification of the intention to market a batch of an immunological veterinary medicinal product, which has a marketing authorisation in the following EC/EEA Member State Hungary and has received an EC Batch release certificate after OBPR or OCABR in another Member State in accordance with Article 81 or Article 82 of EC Directive2004/28/EC and in view of mutual recognition.

Trade name in the above mentioned Member State:	Bovilis BVD
International non-proprietary name / Ph. Eur. name / common name:	Bovine viral diarrhoea vaccine (inactivated).
Name and address of Marketing Authorisation Holder (MAH) for the above mentioned Member State:	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer Represented by the local company
Market authorisation number in the above mentioned Member State:	2974/1-5/11 MgSzH ÁTI
Identification numbers associated with the lot to be marketed in the above mentioned Member State;	
Bulk number (final formulated bulk):	**A099**
Final lot number:	**A099A**
Packaging lot number (if different from final lot n°):	**A099A03**
Batch number of diluent: (where appropriate)	-
Type of Container:	PET Bottles
Number of doses/volume of container:	10
Total number of containers to be marketed in the above noted Member State:	440
Proposed date of marketing:	After approval batch release
Assigned expiry date for this lot in the above noted Member State:	Jul-2015

CA/OMCL performing batch release:	PEI
Type of certificate: (i.e.: OCABR or OBPR)	OBPR
Official batch release certificate number:	20228/14

I hereby declare that:
- this batch is in compliance with the above marketing authorisation and the relevant European Pharmacopoeia monographs;
- this batch is the batch referred to in the accompanying batch release certificate;
- a copy of the batch release certificate (in the case of OCABR with the annexed test results) and the manufacturer's protocol are attached.

Signature of qualified person (MAH):	
Name of qualified person (MAH):	
Date of issue:	

P.G. Meeren
Qualified Person
20 OCT 2014

Use of the following section is optional

For completion by the CA/OMCL after submission:

Date received:	
Signature of qualified authority (CA/OMCL):	
Name of qualified authority (CA/OMCL):	
Decision and Date:	

20-Oct-2014/mw

EDQM ♦ OCABR/OBPR of IVMPS 2010

Trade register No: 16028015

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Paul-Ehrlich-Institut Postfach D-63207 Langen

Intervet Deutschland GmbH
Feldstraße 1a
D - 85716 Unterschleißheim

Reference Number: 20228/14
Administrative Code: 4/3:2.03.01.0094
Date of Release of Certificate: 01.08.2014

EU/EEA OFFICIAL BATCH PROTOCOL REVIEW
CERTIFICATE OF APPROVAL
FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Examined under Article 81 of Directive 2001/82/EC as amended by Directive 2004/28/EC

Trade name:	Bovilis BVD-MD
International non-proprietary name / Ph. Eur. name / common name:	Bovine viral diarrhoea vaccine (inactivated)
Name and address of manufacturer responsible for batch release:	Intervet International B.V. Wim de Körverstraat 35 P.O. Box 31 NL-5830 AA Boxmeer
Marketing authorisation number (Member State / EC):	180a/96
Manufacturer's batch number(s): - final bulk no - final lot no - packaging lot no	A099 A099A A099A01-10
Batch number of diluent (where appropriate):	-
Type of container:	Glass Bottles
Total number of containers of this batch:	30
Number of doses/volume per container:	25
Date of start of period of validity:	21.01.2014
Expiry date:	06.2015

This batch has been examined using documented procedures that form part of a quality management system.

The signed manufacturer's release protocol for this batch has been examined in conformity with Article 81.

This batch is in compliance with all of the approved specifications laid down in the above noted marketing authorisation.

Fees are laid down separately.

PAUL-EHRLICH-INSTITUT LANGEN

Rolf Beck

Mr. Rolf Beckmann

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

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07.08.2014

Bovilis BVD-MD
Marketing Authorisation No.: 180a/96
Batch No.: A099A01-10

Correction

The European Community/EEA Official Batch Protocol Review Certificate of Approval for Immunological Veterinary Medicinal Products, dated 01.08.2014 for batch A099A01-10 (Reference No. 20228/14) of the product Bovilis BVD-MD is changed as follows:

- **Total number of container of this batch: 30,252**
- **Number of doses/volume per container: 10**

Reasons:

- The a.m. certificate contains the erroneous information:

- **Total number of container of this batch: 30**
- **Number of doses/volume per container: 25**

This was an obvious mistake caused by an oversight on the Authoritie`s part which is hereby corrected.

Fees:
No fees are charged.

On behalf of the Paul-Ehrlich-Institut

Mr. Rolf Beckmann

PAUL-EHRLICH-INSTITUT LANGEN

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Aktenzeichen: 4/3: 2.03.01.0094
Ihr Zeichen:

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Fachgebiet 4/3
Abteilung Veterinärmedizin

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Fax +49 (0) 6103 77 1254
Ingun.Lemke@pei.de

11.08.2014

Bovilis BVD-MD, Marketing Authorisation Number 180a/96
Amendment of the European Community/EEA Official Batch Protocol Review Certificate of Approval for Immunological Veterinary Products, batch no. A093B01-10
Re: Correction of the type of container

AMENDMENT

Hereby the certificate concerning the release for batches **A098A01-10** and **A099A01-10** of the product **Bovilis BVD-MD**, marketing authorisation number **180a/96**, dated 01.08.2014 (ref no. 20220/14 and 20228/14) shall be amended as follows:

Type of container	PET bottles

Justification:
The certificates dated 01.08.2014 are amended according to § 42 VwVfG (German Administrative Procedures Law) as an incorrect type of containers (glass bottles instead of PET bottles) was erroneously given.

By order

Dr. Ingun Lemke