



BSE/TSE STATEMENT

To Whom it may concern

According to the documents below:

- Monograph of European Pharmacopoeia chapter 5.2.8 *"Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products"*
- *"Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products"* (EMA/410/01 Rev 3 – March 2011).
- FDA's Code of federal Regulations Title 9 section 94.18

The Quality Manager declares:

- That all products listed in appendix 1 and which contain materials derived from animals, come from countries with negligible BSE risk according to applicable OIE Resolution,
- That the processing facility of bioMérieux Craponne site doesn't receive, store or process any infectious bovine or ruminant material (except: gelatin, tallow derivatives, milk / milk products, hides, and /or vitamin D derived from sheep wool grease) originated from any affected BSE country.

bioMérieux would like to point out that the products mentioned above are intended for in vitro diagnostic use and/or for laboratory microbiological controls, and should not be used as manufacturing material (e.g. seed stock culture preparation, industrial scale fermentation, etc...) and that it is our customers' responsibility to validate and implement a cleaning procedure for their equipment after the use of this product.

Given this statement, the Quality Manager hereby attests that all products manufactured on bioMérieux Craponne site present no risk of BSE/TSE to the final customer.

Validated date of the document: 3 years

Craponne, September 02, 2024

FOURCHE Karen

bioMérieux Craponne Quality Manager



DECLARATION BSE/TSE

Cette déclaration concerne

Selon les documents ci-dessous :

- Monographie de la pharmacopée Européenne 5.2.8 "*Réduction du risque de transmission des agents des encéphalopathies spongiformes animales par les médicaments à usage humain et vétérinaire*"
- "*Note explicative concernant la réduction du risque de transmission des agents des encéphalopathies spongiformes animales par les médicaments à usage humain et vétérinaire*" (EMA/410/01 Rev 3 – March 2011).
- FDA's Code of federal Regulations Title 9 section 94.18

Le Responsable Qualité :

- Déclare que tous les produits listés en annexe 1 et qui contiennent des matières premières d'origine animale proviennent d'animaux de pays à risque négligeable d'ESB conformément à la résolution OIE en vigueur,
- Certifie que les locaux de fabrication du site de bioMérieux Craponne ne reçoivent pas, ne stockent pas, ne mettent pas en œuvre de composant infectieux de bovins ou de ruminants (à l'exception : de la gélatine, des dérivés de suif, du lait/ produits laitiers, des cuirs et/ou vitamines D3 dérivées de la graisse de laine de mouton) provenant de pays où des cas d'ESB ont été déclarés.

bioMérieux souhaite préciser que les produits mentionnés en annexe 1 sont destinés à un usage du diagnostic in vitro et / ou à des laboratoires de contrôle microbiologiques, et ne doivent pas être utilisés comme matériau de fabrication (par exemple semences, préparation stock de culture, fermentation à l'échelle industrielle, etc...), et qu'il est de la responsabilité de nos clients de valider et de mettre en œuvre une procédure de nettoyage pour leurs équipements après l'utilisation de ce produit.

Suite à cette déclaration, le Responsable Qualité atteste que toute la production sur le site de bioMérieux Craponne ne présente aucun risque de ESB/EST pour ses clients.

Date de validité du document: 3 ans


Craponne, le 02 Septembre 2024

FOURCHE Karen
Responsable Qualité bioMérieux Craponne

BSE/TSE STATEMENT

Product reference	Container	Product name
41995	Bottles	PORTAGERM 10VIALS
42041	Bottles	PORTAGERM PYLORI 8VIALS
43001	Plates	TRYPCASE SOY AG.5% SH.BL.20 PL
43004	Plates	CHROMID VRE ID AGAR 20 PLT
43009	Plates	TRYPCASE SOY AG+SH.BL. 100PLTE
43011	Plates	TRYPCASE SOY AGAR 20 PL
43019	Plates	GELOSE TRYPCASE-SOJA 100 PLA.
43021	Plates	PURPLE LACTOSE AGAR 20 PL
43031	Plates	LEGIONELLA (GVPC) MEDIUM 20P
43032	Plates	LEGIONELLA GVPC MEDIUM 100 PLT
43041	Plates	COLUMBIA 5% SHEEP BL. 20 PLA.
43049	Plates	G.COLUMBIA 5%SG MOUTON 100 BOX
43050	Plates	COLUMBIA AGAR+5%HORSE BLOOD20P
43061	Plates	TRYPCASE SOY AG.5% HOR.BL20PLT
43071	Plates	COLUMBIA CNA 5% SHEEP BD 20PLT
43079	Plates	G.COLUMBIA CNA 5%SG MT 100PLAT
43081	Plates	EOSIN METHYLENE BL.AGAR 20PLT
43091	Plates	SALMONELLA SHIGELLA AGAR 20PLT
43099	Plates	G.SS 100BTES
43101	Plates	CHOCOLATE AGAR+POLYVITEX 20PL.
43109	Plates	G.CHOCOLAT POLYVITEX 100PLATES
43111	Plates	HEKTOEN ENTERIC AGAR 20 PLT
43119	Plates	G.HEKTOEN 100BTES
43141	Plates	MC CONKEY CRYSTAL VIOLET 20PLT
43149	Plates	GELOSE MAC CONKEY 100 PLATES
43151	Plates	D-COCCOSEL 20PLT
43169	Plates	TSA 3P IRR 100 PLT
43209	Plates	G.YERSINIA CIN 100BTES
43279	Plates	G.SCHAEDLER 5% SG MOUTON 100
43287	Plates	TSA 3P IRR BETALACTAMASE
43288	Plates	COUNTTACT 3P IRR BETALACTAMASE X20
43321	Plates	M.HINTON 2 SHEEP BLOOD 90 20PL
43329	Plates	MUELLER HINTON2+5% SH.BL. 100P
43331	Plates	CLED 20PLT
43339	Plates	CLED AGAR 100 BTES
43341	Plates	DRIGALSKI 20PLT
43361	Plates	CAMPYLOSEL 20PLATES
43391	Plates	GELOSE CT SMAC 20 PLATES
43401	Plates	SCHAEDLER 5% SHEEP BLOOD AGAR
43411	Plates	GARDNERELLA AGAR 20 PLTS
43421	Plates	YERSINIA CIN AGAR 20 PLTS
43431	Plates	CLOSTRIDIUM D. AGAR 20 PLTS
43451	Plates	CHROMID MRSA 20 PLT

BSE/TSE STATEMENT

Product reference	Container	Product name
43459	Plates	CHROMID MRSA 100 PLT
43461	Plates	CHROMID STREPTO B 20 PLT
43464	Plates	CHROMID CANDIDA SABOURAUD 20PL
43466	Plates	CHROMID MRSA S. AUREUS 20 PLT
43467	Plates	GRANADA/COL CNA AGAR
43470	Plates	CHROMID ESBL / CHROMID VRE
43471	Plates	CAMPYFOOD AGAR 20 PLATES
43474	Plates	MACCONKEY/COL CAN 20 PLATES
43481	Plates	CHROMID ESBL 20 PLT
43501	Plates	COUNT-TACT 20PLT
43521	Plates	GELOSE BAIRD PARKER - 20 PLATES - 90MM
43531	Plates	GELOSE BAIRD PARKER RPF (RPFA) - 20 BTES
43551	Plates	R2A - GELOSE 20PLATES
43555	Plates	SABOURAUD DEXTROSE AGAR
43563	Plates	XLD AGAR
43564	Plates	XLD AGAR 100PLATES
43565	Plates	CETRIMIDE AGAR
43580	Plates	SABOURAUD DEXTROSE CONTACT
43596	Plates	SAB DEXTROSE CHL AGAR 20PLT
43601	Plates	BRILLANT GREEN AGAR 20PLATES
43611	Plates	CHOCOLATE AGR POLYVITEX VCAT3
424326	Plates	CHROMID SALMONELLA 20 PLATES
43631	Plates	CHROMID CANDIDA 20 PLATES
43639	Plates	CHROMID CANDIDA 100 PLATES
43651	Plates	SABOURAUD GENTA.CHLOR 2 20 PLT
43659	Plates	SABOURAUD GENTA.CHLOR 2 100PLT
43661	Plates	CHROMID LMONO 20 PLTS
43671	Plates	CHAPMAN 2 MEDIUM 20 PLATES
43681	Plates	CHOCOLAT HAEMOPH. 2 MEDIUM 20P
43689	Plates	CHOCOLAT HAEMOPH.2 MEDIUM 100P
43691	Plates	COUNT-TACT IRR 3P X20
43699	Plates	COUNT-TACT IRR 3P X100
43711	Plates	TSA 3P IRR 20 PLATES
43811	Plates	TSA 3P IRR NEUTRALIZERS X20
43812	Plates	CT SAB DEX 3P IRR NEUTRALIZERS
43814	Plates	SAB DEX 3P IRR NEUTRALIZERS
43819	Plates	TSA 3P IRR NEUTRALIZERS X100
43841	Plates	CHROMID MRSA 20 PLT US
43861	Plates	CHROMID CARBA AGAR 20 PLT
43871	Plates	CHROMID C.DIFFICILE 20 PLT
43901	Plates	M.HINTON HORSE BLOOD NADX20PLT
43919	Plates	M.HINTON HORSE BLD NADX100BTS
51009	Dehydrated medium	BRAIN HEART INFUSION 500G
51015	Dehydrated medium	MAC CONKEY BROTH 500G

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Product reference	Container	Product name
51018	Dehydrated medium	THIOGLYCOLLATE BROTH RES.500G
51019	Dehydrated medium	TRYPCASE-SOY BROTH 500G
51020	Dehydrated medium	AGAR SABOURAUD 2 500G
51021	Dehydrated medium	AGAR SABOURAUD CHLOR 2 500G
51025	Dehydrated medium	D-COCCOSEL AGAR 500G
51026	Dehydrated medium	COLUMBIA AGAR, 500G
51033	Dehydrated medium	EOSIN METHYLENE BLUE AG. 500G
51035	Dehydrated medium	PURPLE LACTOSE AGAR 500G
51036	Dehydrated medium	MACCONKEY AG WITHOUT CVIO500G
51039	Dehydrated medium	BLOOD AGAR BASE 500G
51043	Dehydrated medium	SALMONELLA SHIGELLA AGAR 500G
51044	Dehydrated medium	TRYPCASE-SOY AGAR 500G
51047	Dehydrated medium	TRIPLE SUGAR IRON AGAR 500G
51049	Dehydrated medium	XLD AGAR 500G
51050	Dehydrated medium	HEKTOEN ENTERIC AGAR 500G
51052	Dehydrated medium	CLED AGAR 500G
51053	Dehydrated medium	MANNITOL SALT AGAR 500G
51072	Dehydrated medium	STANDARD METHODS AGAR 500G
51075	Dehydrated medium	MUELLER HINTON 2 AGAR 500G
51101	Dehydrated medium	IRR TSB ANI PEPT 3P MFT 5KG
51102	Dehydrated medium	IRR TSB ANI PEPT 3P MFT 500G
51140	Dehydrated medium	TRYPCASE SOY BROTH 5 KG PS
51280	Dehydrated medium	COLUMBIA AGAR BASE 5 KG PS
410782	Dehydrated medium	IRRADIATED TSB 3P VP 5KG
410783	Dehydrated medium	IRRADIATED TSB 3P VP 500G
410927	Plates	CT3P+ENHANCED NEUTRALIZER X20
411968	Plates	BRUCELLA BLOOD AGAR 20 PLT
412108	Plates	CHROMID SALMONELLA ELITE 20 PLTS
413050	Plates	CHROMID MRSA SMART 20 PLATES
413051	Plates	CHROMID MRSA SMART 100 PLATES
413194	Plates	SCHAEGLER NEO.VANC.5%SB 20PLT
413822	Plates	MUELLER HINTON E AGAR 90 20PL
413824	Plates	MUELLER HINTON E AGAR 90 100PL
414011	Plates	CHROMID OXA 48 20 PLTS
414524	Plates	CHROMID MRSA S. AUREUS US
414685	Plates	CHROMID CARBA SMART
416172	Plates	CHROMID CPS ELITE TRANSLUCENT 100 PLT
416173	Plates	CHROMID CPS ELITE OPAQUE AGAR 100 PLTS
418206	Plates	CHROMID CPS ELITE OPAQUE 20 PT
418229	Plates	CHROMID CPS ELITE / COL CNA
418284	Plates	CHROMID CPS ELITE TRANSLUCEN 20 PLT
419042	Plates	CHROMID S.AUREUS ELITE 20 PL
419751	Plates	CHROMID STREPTO B US 20 PLT
419398	Plates	CHROMID SMART MRSA/S.AUREUS 20 PLT

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Product reference	Container	Product name
420984	Dehydrated medium	LPT Broth (LPT-D) 500G
420985	Dehydrated medium	LPT Broth (LPT-D) 5KG
423144	Plates	NTM ELITE AGAR
423850	Plates	ASAP AGAR 90MM - 20 PLATES
424093	Plates	PCA 20 PLATES - 90MM
424094	Plates	PCA 100 PLATES - 90MM
424096	Plates	GELOSE BAIRD PARKER - 100 PLATES
424097	Plates	GELOSE BAIRD PARKER RPF (RPFA) - 100 BTES
424131	Plates	ASAP AGAR 90MM - 100 PLATES
424235	Plates	GELOSE SABOURAUD GLUCOSE CHLORAMPHENICOL (SDC) - 100 PLATES