

EC DECLARATION OF CONFORMITY

Company:	EC Representative:
Meridian Bioscience, Inc. 3471 River Hills Drive Cincinnati, OH 45244 USA	Meridian Bioscience Europe SRL Via dell' Industria, 7 20035 Villa Cortese, Milano Italy
Catalog#/Product:	See Appendix 1 to this document
Risk Classification:	General IVD (others)
Device Type:	In vitro diagnostic device
Conformity Assessment Route:	Annex III of the Directive 98/79/EC
Notified Body:	These are self-certified devices according to the 98/79/EC Directive.
Standards/Regulations applied:	
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012 (ISO 14971:2019)	Medical devices - Application of risk management to medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk infection related to in vitro diagnostic reagents
EN ISO 18113-1:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions, and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling) - Part 2: In vitro diagnostic reagents for professional use
EN 62366-1: 2015 ^{1,2}	Medical Devices - Part 1: Application of Usability and Human Factors Engineering to medical devices

¹ Product(s) developed prior to the implementation of the EN 62366-1 standard.

² Product has not been evaluated for compliance to the EN 62366-1 standard.

We herewith declare that the products identified in this Declaration comply fully with the applicable *Essential Principles for Safety and Performance*, meet the essential requirements of Annex I of the Council Directive 98/79/EC for medical devices and carry the CE mark. All supporting technical documentation (product, process and quality system specific) is retained on the premises of Meridian Bioscience, Inc.

Date of issue: April 21, 2022

Signed: 

Name: Jack Rogers

Title: Regulatory Affairs Principal

Appendix 1 to Declaration of Conformity – *In vitro* Diagnostic Device

Catalog #	Product Name
Curian® Immunoassays	
760130	Curian® HpSA®
760730	Curian® Campy
Catalog # Product Name	
alethia® Molecular Amplification Assays	
480050	alethia® C. difficile
479920	alethia® C. difficile External Control Kit
480350	alethia® Group B Streptococcus
479900	alethia® Group B Streptococcus External Control Kit
480150	alethia® Group A Streptococcus
479910	alethia® Group A Streptococcus External Control Kit
480250	alethia® Mycoplasma Direct
479890	alethia® Mycoplasma Direct External Control Kit
480650	alethia® HSV 1&2
479960	alethia® HSV 1&2 External Control Kit
480750	alethia® Pertussis
479930	alethia® Pertussis External Control Kit
480850	alethia® Gonorrhea
480925	alethia® Malaria
481125	alethia® Malaria Plus
479970	alethia® Malaria External Control Kit

Catalog #	Product Name
C. difficile Assays	
712050	ImmunoCard® Toxins A&B ¹
616096	PREMIER® Toxins A&B ¹
716050	ImmunoCard® C. difficile GDH
611096EU	PREMIER® C. difficile GDH (FOR EXPORT USE ONLY)
Cryptococcal Antigen and Coccidioides Assays ¹	
603096	PREMIER® Coccidioides EIA
140100	CALAS® Cryptococcal Antigen Latex Agglutination System (Includes 140050 CALAS® Pronase)
602096	PREMIER® Cryptococcal Antigen
Cryptosporidium/Giardia Assays	
750830	ImmunoCard STAT!® Crypto/Giardia ²
750820	ImmunoCard STAT!® Crypto/Giardia Control ²
751420	ImmunoCard STAT!® CGE ²
751403	ImmunoCard STAT!® CGE Positive Control ²
250050	MERIFLUOR® Cryptosporidium/Giardia ²

R2206	MERIFLUOR® Treated Slides ¹
Foodborne Illness Assays -- E. coli/Shigatoxin ¹	
751630	ImmunoCard STAT!® EHEC
608096	PREMIER® EHEC
750530	ImmunoCard STAT!® E. coli O157 Plus
Foodborne Illness Assays -- Campylobacter	
618096	PREMIER® CAMPY
751530	ImmunoCard STAT!® CAMPY
H. pylori Assays	
750720	ImmunoCard STAT!® HpSA® ¹
750220	ImmunoCard STAT!® HpSA® ¹
750005	ImmunoCard STAT!® HpSA® HD
750020	ImmunoCard STAT!® HpSA® HD
601396	PREMIER Platinum HpSA® PLUS
710030	ImmunoCard® H. pylori ¹
606096	PREMIER® H. pylori ¹

Catalog #	Product Name
Immunodiffusion and complement fixation reagents ¹	
100601	Anti-Histoplasma Control Serum (Goat) for Fungal Immunodiffusion
100401	Coccidioides F Antigen for Fungal Immunodiffusion
100405	Coccidioides F Antigen for Fungal Immunodiffusion
103001	Coccidioides TP Antigen for Fungal Immunodiffusion
100801	Anti-Coccidioides F Control Serum (Goat) for Fungal Immunodiffusion
103101	Anti-Coccidioides TP Control Serum (Goat) for Fungal Immunodiffusion
101012	Immunodiffusion Plates – Series 1
101009	Immunodiffusion Plates – Series 4
Immunology Assays	
102505	Histoplasma (Yeast Phase Whole Cell) ¹
100201	Histoplasma Antigen for Fungal Immunodiffusion ¹
EB100	MERIFLUOR® EBV IgG IFA ¹
EB150	MERIFLUOR® EBV IgM IFA ¹
EA101	MERIFLUOR® EBV-EA IgG IFA ¹
EN100	MERIFLUOR® EBV-NA IFA ¹
EB211	MERIFLUOR® EBV VCA IgG/IgM IFA Slide Pack ¹
751730	TRU EBV-M®
751830	TRU EBV-G®
XX715	MERIFLUOR® GullSORB 5 mL ¹
Microbiology Assay	
755250	ImmunoCard STAT!® Strep A ²
Mononucleosis Assays	
755725	ImmunoCard STAT!® MONO ²
776150	MONOSPOT® Latex ¹

<i>Adenovirus/Rotavirus Assays¹</i>	
750030	ImmunoCard STAT! [®] Rotavirus
696004	PREMIER [®] Rotaclone [®]
696007	PREMIER [®] Adenoclone [®]
696006	PREMIER [®] Adenoclone [®] 40/41
<i>Upper Respiratory Assays</i>	
751330	TRU RSV ^{® 1}
751110	RSV Positive Control ¹
709030	ImmunoCard [®] Mycoplasma ¹
222030	MERIFLUOR [®] Pneumocystis ¹
751930	TRU LEGIONELLA [®]
752330	TRU STREP PNEUMO [®]

Catalog #	Product Name
<i>Viral Direct Fluorescent Assays and Transport Medium</i>	
505021	Meridian Viral Transport ²
500113	MERIFLUOR [®] VZV ¹
500500	MERIFLUOR [®] Phosphate Buffered Saline ¹
<i>Enzyme-linked Immunosorbent Assay</i>	
4884261	ANA Screening ELISA ²

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