Declaration of Conformity

Document No: DOCDCM001

Issue No: 01

For Dehydrated Culture Media IVD Product Range

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

Neogen declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Neogen Culture Media
Legal Manufacturer: (Name on Label)	Neogen Europe Limited 1 Quest Park, Moss Hall Road, Heywood, England, UK, BL9 7JJ
SRN:	GB-MF-000033239
Basic UDI-DI:	50566908DCMW8
Variants:	Dehydrated culture media supplied in 500g, 5kg, 10kg and 25kg volumes: Product Code / Appearance NCM****A – 500g bottle NCM****B – 5 kg pail NCM****C – 10 kg pail NCM****D – 25 kg drum
IVDR Classification:	Class A
Notified Body:	N/A
EU Authorised Representative:	CS Lifesciences Europe Limited The Black Church, St. Mary's Place, Dublin 7, Ireland, D07 P4AX
EU Authorised Representative SRN:	IE-AR-000004113
IVDR Assessment Route:	Annex I, II and III

Product Name	Product Code(s)	Intended Purpose
Columbia Agar Base CE	NCM2010	Columbia Agar Base is used with blood for the isolation and cultivation of a wide variety of fastidious microorganisms.
Mannitol Salt Agar CE	NCM2011	Mannitol Salt Agar is used for the isolation of staphylococci in a clinical laboratory setting.
Sabouraud Dextrose Agar CE	NCM2012	Sabouraud Dextrose Agar is used for the cultivation of fungi and yeasts.
Blood Agar Base No. 2 CE	NCM2013	Blood Agar Base No. 2 is used with blood for the isolation and cultivation of a wide variety of fastidious microorganisms.

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Blood Agar Base CE	NCM2014	Blood Agar Base is used with blood for the isolation and cultivation of a wide variety of fastidious microorganisms.
Xylose Lysine Deoxycholate (XLD) Agar CE	NCM2015	Xylose Lysine Deoxycholate (XLD) Agar is a selective agar for the detection of Salmonella spp.
Mueller Hinton Agar I CE	NCM2016	Mueller Hinton Agar I is used for antimicrobial sensitivity testing by the disc diffusion method.
Cystine Lactose Electrolyte Deficient (CLED) Agar CE	NCM2017	Cystine Lactose Electrolyte Deficient (CLED) Agar is used for the differentiation and enumeration of microorganisms in urine.
MacConkey Agar No. 3 CE	NCM2018	MacConkey Agar No. 3 is used for the cultivation of *Enterobacteriaceae*.
Salmonella Shigella (SS) Agar CE	NCM2019	Salmonella Shigella (SS) Agar is used for the isolation of *Salmonella* spp. and some strains of *Shigella* spp.
Fastidious Anaerobe Agar CE	NCM2020	Fastidious Anaerobe Agar is used for the cultivation of anaerobic microorganisms
Hektoen Enteric (HE) Agar CE	NCM2021	Hektoen Enteric Agar is used for the isolation and differentiation of enteric pathogens.
Campylobacter Blood-Free Selective Medium (Modified CCDA) CE	NCM2022	Campylobacter Blood-Free Selective Medium (Modified Charcoal Cefoperazone Deoxycholate Agar or mCCDA) is used for the cultivation of *Campylobacter* spp. in clinical laboratories.
Columbia Blood Agar Base CE	NCM2023	Columbia Blood Agar Base is used with blood for the isolation and cultivation of a wide variety of fastidious microorganisms.
MacConkey Agar No.2 CE	NCM2024	MacConkey Agar No.2 is a modification of MacConkey Agar which contains bile salts No. 2 for the recognition of Enterococci.

Name	Samantha Cowley	**Position**	Quality & Regulatory Manager
Signed		**Date**	03Oct2023
Place	United Kingdom		

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Appendix I – Applicable Standards
This present declaration is also in conformity with the following European standards:

Standard/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements