Declaration of Conformity

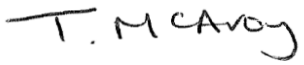
Document No: DOCNCM4029
Issue No: 01

For Neomycin (100mg/L) CE (NCM4029)

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:	50566908SUPPVY
Product Code:	NCM4029 – 0.5
Product Name:	Neomycin (100mg/L) CE
Variants:	None
Intended Purpose:	A selective supplement for the isolation of *Clostridium* spp. for use with: NCM2013 Blood Agar Base No. 2 CE
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

Name	Tracy McAvoy	**Position**	Head of Quality & Compliance
Signed		**Date**	10Feb2023
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