SELF DECLARATION OF CONFORMITY

We declare under our sole responsibility in accordance with MHRA Registration Number IVD 000100 that the following CE marked products:

EDMA code(s)	EDMA description	TCS product code and description
14.50.01.90	Other Controls/Standards/Calibrators, Microbiology	Selectrol - All MM codes

conform to the relevant provisions of the In-vitro Diagnostic Medical Devices Directive 98/79/EC and The Medical Devices Regulations 2002 (SI 2002 No.618) and The Medical Devices (Amendment) Regulations 2003 (SI 2003 No.1697) for in-vitro diagnostic medical devices.

This declaration is made on the basis of meeting the requirements of Annexes I and III of the In-Vitro Diagnostic Medical Devices Directive 98/79/EC and continued maintenance of an approved Quality Management System meeting the requirements of ISO 9001, as certified by BSi, certificate number FS 28907.

Signed by: Sue Brown Date: 30.04.2016

Name: Sue Brown
Position: Regulatory Affairs Manager

Signed by: Lynda Preston Date: 30.04.2016

Name: Lynda Preston
Position: Managing Director

Digitally signed by Monastîrschii Viorica
Date: 2020.10.29 10:09:06 EET
Reason: MoldSign Signature
Location: Moldova

Iss 2/30.04.16