



## DECLARATION OF CONFORMITY

**Conformity Assessment Route: Annex III of the Directive  
98/79/EC on In Vitro Diagnostic Medical Devices**

WE: **RANDOX LABORATORIES LTD.**

55 DIAMOND ROAD, CRUMLIN, COUNTY ANTRIM, BT29 4QY, UK

CERTIFY THAT THE PRODUCT (S) CONFORM (S) TO THE DIRECTIVE 98/79/EC AS TRANSPOSED BY MEDICAL DEVICE REGULATIONS STATUTORY INSTRUMENT 618:2002. THE MANUFACTURER RETAINS ALL SUPPORTING DOCUMENTATION.

PRODUCT CATEGORY: OTHER, NOT SELF TESTING

PRODUCT NAME/ FAMILY: BUFFERS (UNASSIGNABLE), SUPPLEMENTARY REAGENTS (CC)

PRODUCT DETAILS: REFER TO TABLE IN ATTACHMENT 1

THE PRODUCT(S) HAVE BEEN ASSESSED BY APPLICATION OF STANDARDS / SPECIFICATIONS AS LISTED IN THE ESSENTIAL REQUIREMENTS CHECKLIST.

DATE OF FIRST ISSUE: 27 Nov 2003

DATE OF RE-ISSUE: 17 Apr 2018

SIGNATURE:

Dr. Pauline Armstrong

Quality Assurance/ Regulatory Affairs Manager

## ATTACHMENT 1

Catalogue number	Description
DN2830	PURIFIED WATER
DN2841	ENZYME DILUENT
HA3450	HBA1C DENATURANT REAGENT (HB REAG DNT)
RA885	RANDOX ACCESS FLUID (RAF)
RA2632	RANDOX ACCESS FLUID (RAF)
RP3857	REAGENT PRECISION TEST SOLUTION (RABS)
RP8398	REAGENT PRECISION TEST SOLUTION (RABS)
RS2318	RANSEL DILUENT (DIL RANSEL)
RX8142	PRECISION CHECK (PREC)
RX3950	ISE URINE DILUENT (ISE DIL URN)
RX3963	WASH SOLUTION 1 (WASH CONC 1)
RX3962	WASH SOLUTION 2 (WASH CONC 2)
RX3946	WASH SOLUTION 3 (WASH CONC 3)
RX3973	C1 SOLUTION (C1 SOLN)
RX4000	ISE CALIBRATOR A (CAL A)
RX4003	ISE CLEANING SOLUTION (SOLN WASH)
RX4044	L SOLUTION (L SOLN)
RX4045	REFERENCE SOLUTION (REF SOLN)
RX4046	H SOLUTION (H SOLN)
RX4047	I.S.E. CLEANER (ISE CNL)
RX4048	ETCHING (ETCH)
RX4049	I.S.E. DILUENT (ISE DIL)
RX8104	CONCENTRATED WASH SOLUTION (WASH CONC)
RX8105	ISE DETERGENT
RX8106	DETERGENT
RX8107	ACIDIC DETERGENT
RX8108	ALKALINE DETERGENT
RX8109	REFERENCE ELCTRODE DETERGENT
RX8110	ISE STANDARD LIQUID
RX8111	ISE DILUENT
RX8126	ISE BUFFER (ISE BUF)
RX8127	ISE L SOLUTION (L SOLN)
RX8128	ISE DETERGENT (ISE DET)
RX8129	ACID WASH SOLUTION (WASH SOLN 3)
RX8130	ALKALINE WASH SOLUTION (WASH SOLN 9)
RX8142	REAGENT PRECISION TEST SOLUTION (PREC)
RX8143	C1 WASH SOLUTION (C1 SOLN)
RX9001	ACCESSORY BOX
SA3854	SALINE DILUENT (NS)
SA8396	SALINE DILUENT (NS)
SD124	RANSOD DILUENT
SP3856	SAMPLE PRECISION TEST SOLUTION (SABS)
SP8399	SAMPLE PRECISION TEST SOLUTION (SABS)
TBX2814	TxB CARDIO SAMPLE DILUENT
WS3853	ACID WASH SOLUTION (AWS)
WS8397	ACID WASH SOLUTION (AWS)
ZN2607	ZINC DEPROTEINISING SOLUTION (Zn)