

→ **Biorex Diagnostics Limited**

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## EC Declaration of Conformity (Directive 98/79/EC)

**Manufacturer:** Biorex Diagnostics Limited, Unit 2C Antrim Technology Park, Antrim, United Kingdom,  
BT41 1QS

**Manufacturer Identification:** NI 48247

**Competent Authority:** Medicines and Healthcare Products Regulatory Agency (MHRA), Competent  
Authority GB/CA01

**Product Details:** See MHRA Letter and list attached.

**Classification:** IVD, Non Annex II, Self-Declaration

**Conformity Assessment Route:** Annex IV IVDD, Full Quality Assurance

We, Biorex Diagnostics Limited, hereby declare that the devices named in the attached list comply with and confirm to the directives and standards of DIRECTIVE 98/79/EC IVD MEDICAL DEVICES Annex II.

**Standards Applied:** EN ISO 9001:2008, EN ISO13485:2003, EN ISO 9001:2000

**Signed:** \_\_\_\_\_

**Name:** Mervyn Russell

**Biorex Diagnostics Ltd**  
**www.biorexdiagnostics.com**

**Position:** Export Development Manager

**Place:** Biorex Diagnostics Limited

**Date:** 1<sup>st</sup> June 2016

## 2016 PRODUCT LIST



### CONTENTS

	PAGES
SECTION ONE - CLINICAL CHEMISTRY REAGENTS	2 - 16
SECTION TWO - HITACHI SYSTEM REAGENTS	17 - 25
SECTION THREE - OLYMPUS SYSTEM REAGENTS	26 - 29
SECTION FOUR - CA 180 / CA 270 / CA400 FURUNO / DAYTONA SERIES REAGENTS	30 - 35
SECTION FIVE - QUALITY CONTROLS & CALIBRATORS	36 - 47
SECTION SIX - AQUEOUS STANDARDS	48 - 49
SECTION SEVEN - IMMUNOASSAYS (ELISA)	50 - 57
SECTION EIGHT - CLIA	58 - 59
SECTION NINE - SYPHILIS	60
SECTION TEN - FEBRILE ANTIGENS	61 - 62
SECTION ELEVEN - LATEX SEROLOGY	63 - 64
SECTION TWELVE - BLOOD GROUPING	65 - 68
SECTION THIRTEEN - RAPID TESTS	69 - 70
SECTION FOURTEEN - HAEMATOLOGY REAGENTS	71
SECTION FIFTEEN - HAEMOSTASIS	72 - 74
SECTION SIXTEEN - URINE TEST STRIPS	75
SECTION SEVENTEEN - FOOD & FEED DIAGNOSTICS	76 - 77
SECTION EIGHTEEN - INSTRUMENTATION	78 - 79
SECTION NINETEEN - SERAQUAL EXTERNAL QUALITY ASSESSMENT SCHEME	80 - 81

2016 PRODUCT LIST

Cat.No.	Description	Methodology	Size
<b>SECTION EIGHTEEN - INSTRUMENTATION</b>			
<b>CLINICAL CHEMISTRY ANALYSERS</b>			
FORT2010	Analyst 2010	Semi-Automated Chemistry Analyzer	Manual
MON0240S	Monarch-240	Fully-Automated 240 Tests/Hour Bench Top Chemistry Analyzer	240 T P/H
MON0300S	Monarch-300	Fully-Automated 300 Tests Hour Chemistry Analyzer	300 T P/H
MON0400S	Monarch-400	Fully-Automated 400 Tests Hour Chemistry Analyzer	400 T P/H
MON0600S	Monarch-600	Fully-Automated 600 Tests Hour Chemistry Analyzer	600 T P/H
MON0800S	Monarch-800	Fully-Automated 800 Tests Hour Chemistry Analyzer	800 T P/H
MONISE00	Monarch-ISE-MODULE	ISE MODULE FOR MONARCH 400/600/800	
<b>IMMUNOASSAY ANALYSERS</b>			
FORTMRS1	Microscan	Automatic Microplate Reader	
FORTMRS2	Microscan Mini	Compact 8-channel Microplate Reader	
FORTMW1	Innowash	Automatic Microplate Washer	
FORTBIO2	BIO-2 +	2 Plates Fully Automated ELISA Processor	
<b>CLIA ANALYSERS</b>			
CLIAPRO1	CLIA PRO	Microstrip Chemiluminescence Reader	
CLIAPLUS	CLIA PLUS	Microplate Chemiluminescence Reader	
<b>HAEMATOLOGY ANALYSERS</b>			
CELLDIF3	Haematology CELLDIFF-3+	3 Part Differential, 18 Parameters	
CELLDIF5	Haematology CELLDIFF-5+	5 Part Differential, 24 Parameters	