



DECLARATION Number:
ACCURUN 1 Multi-Marker
Control Family

EC DECLARATION OF CONFORMITY

Annex II List A Medical Devices For In vitro Diagnostic

We

LGC Clinical Diagnostics, Inc.
37, Birch Street
Milford, MA 01757 U.S.A.

having designated :
MEDIMARK® Europe Sarl, 11 rue Émile Zola – BP 2332
38033 Grenoble Cedex 2 - France
as our European Authorized Representative,

having been assessed by British Standards Institution, Notified Body Number 2797, in accordance with Annex IV.3 of the Directive 98/79/EC on In Vitro Medical Devices (Certificate No. CE 575325), and with Annex IV.4 (Certificate No. 572687), insure and declare under our sole responsibility that the Annex II List A devices specified in the attached list to which this declaration relates are in conformity with the requirements of Annex I of the Directive 98/79/EC on In Vitro Medical Devices.

This declaration is made in accordance with Annex IV of the Directive 98/79/EC on In Vitro Medical Devices and is valid for an undetermined period of time.

Milford, MA U.S.A.

Original issue: August 26, 2011
Revision Date Sept 22, 2021

Name of authorized person: Prajakta Buva
Title: RA Specialist

Signature:



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Annex II List A Medical Devices For In vitro Diagnostic in relation with the above declaration

Product description	Part Number	Material number
ACCURUN® 1 Multi-Marker Negative Control	A001-1001-N	2010-0013
ACCURUN® 1 Multi-Marker Negative Control	A001-1008-N	2010-0015
ACCURUN® 1 Multi-Marker Positive Control, Series 2400	A001-2408-P	2000-0001
ACCURUN® 1 Multi-Marker Positive Control, Series 2500	A001-2508-P	2000-0002
ACCURUN® 1 Multi-Marker Positive Control, Series 2700	A001-2705-P	2000-0005
ACCURUN® 1 Multi-Marker Positive Control, Series 4000	A001-4003-P	2000-0008
ACCURUN® 1 Multi-Marker Positive Control, Series 4400	A001-4408-P	2000-0010
ACCURUN® 1 Multi-Marker Positive Control, Series 5100	A001-5103-P	2000-0016
ACCURUN®1 Multi-Marker Positive Control, Series 5100	A001-5108-P	2000-0017
ACCURUN®1 Multi-Marker Positive Control, Series 5600	A001-5605-P	2000-0018
ACCURUN® 1 Multi-Marker Positive Control, Series 8100	A001-8103-P	2000-0022
ACCURUN® 115 Hepatitis B Core IgG Positive Control	A115-5001	2015-0070
ACCURUN® 2 Multi-Marker Positive Control, Series 2700	A002-2705-P	2000-0023
ACCURUN® 2 Multi-Marker Positive Control, Series 2700	A002-2706-P	2000-0024

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