DECLARATION Number:
ACCURUN 106 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. 572693),

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: Sept 19, 2011
Revision Date: Sept 08, 2021

Name of authorized person: Prajakta Buva
Title: RA Specialist
Signature: Buva

DECLARATION Number:
ACCURUN 106 Family

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

Device Designation	Part number	Material Number
ACCURUN® 106 HIV-1 Antigen Positive Quality Control, Series 1000	A106-1003	2015-0065
ACCURUN® 106 HIV-1 Antigen Positive Quality Control, Series 1000	A106-1008	2015-0066

Milford, MA U.S.A.
Original issue: Sept 19, 2011
Revision Date: Sept 08, 2021

Name of authorized person: Prajakta Buva
Title: RA Specialist
Signature: