DECLARATION Nº: ACCURUN Syphilis Control Family

EC DECLARATION OF CONFORMITY
In Vitro Diagnostic Medical Devices for Professional Use

We

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

having designated:
Medimark Europe Sarl ,
11 rue Emile Zola – 38033 Grenoble Cedex 2 – France
as our European Authorized Representative

having our Quality Management System certified against ISO 13485:2016 standard (Certificate N° FM572228 issued by BSI, originally registered date April 11, 2011)

insure and declare under our sole responsibility that the In Vitro Diagnostic Medical Devices specified in the attached list to which this declaration relates are in conformity with the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices.

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

Milford, MA U.S.A.

Original issue:	November 16, 2011
Updated:	Sept 17, 2021

Name of authorized person: Prajakta Buva
Title: RA specialist

Signature: 

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List of Annex 3 In Vitro Diagnostic Medical Devices for professional use in relation with the above declaration

Device designation	Part Number	Material Number
ACCURUN® 155 Anti-Treponema (Syphilis) Positive Control, Series 2000	A155-2010	2015-0090
ACCURUN® 155 Anti-Treponema (Syphilis) Positive Control, Series 5000	A155-5008 A155-5010	2015-0092 2015-0093
ACCURUN® 156 Reagin (Syphilis) Positive Control	A156-5006	2015-0094

Milford, MA U.S.A.

Original issue:	November 16, 2011
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Name of authorized person: Prajakta Buva
Title: RA Specialist

Signature: