DECLARATION OF CONFORMITY

Beckman Coulter Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

EU Directive(s)

Low Voltage (2006/95/EC) 2014/35/EU

Electromagnetic Compatibility (2004/108/EC) 2014/30/EU

Machinery Directive (2006/42/EC)

Product(s):
Intended Use: For *in vitro* diagnostic use only. The Allegra V-15R centrifuge is intended to separate human samples, including blood, urine, and other bodily fluids to prepare samples for downstream in vitro diagnostic procedures, which may include molecular diagnostic, chemistry, immunoassay, and coagulation tests.

Intended User:This centrifuge should be operated by laboratory professionals only.

Device Group:
W02069003

BUDI-DI:
150995901ALLEGRAV15RQ9

Risk Class:
Class A, Rule 5a

Authorized Representative (AR)
Beckman Coulter Ireland, Inc.

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AR SRN: AR-000000886

Intended Purpose:
Intended Use: For *in vitro* diagnostic use only. The Allegra V-15R centrifuge is intended to separate human samples, including blood, urine, and other bodily fluids to prepare samples for downstream in vitro diagnostic procedures, which may include molecular diagnostic, chemistry, immunoassay, and coagulation tests.

Intended User:This centrifuge should be operated by laboratory professionals only.
Clinical Relevance: Not applicable, the centrifuge does not detect or define any clinical condition.

Common Specification(s):
None

Conformity Assessment Procedure:
Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

Signed for and on behalf of Beckman Coulter, Inc. the Legal Manufacturer.

Name: James Taller 2023-11-21
Title: Senior Manager QRA, PRRC
Place of Issue: Beckman Coulter, Inc., Indianapolis, IN USA

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Electrical and Safety Standards

STANDARD NO.	TITLE
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2-101:2017	Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use - Part 2-101: Particular Requirements For In Vitro Diagnostic (IVD) Medical Equipment
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1-General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 61010-2-020:2017	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-020 Particular requirements for laboratory centrifuges
EN IEC 63000-2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances