

EC Declaration of Conformity

Manufacturer: Heathrow Scientific® LLC, 620 Lakeview Parkway, Vernon Hills, IL 60061 USA

European Contact: Emergo, Europe, Princessegracht 20, 2514AP, The Hague, The Netherlands

Product: Clinical Centrifuge

Product Model No(s): 120775, 120776

Risk Class: Class A, Rule 5a (Article 47, Annex VIII) per IVDF 2017/746

Intended Purpose (IVDR 2017/746)	
What is to be detected or measured?	Not applicable. This centrifuge does not detect or measure any analyte.
Device function such as, screen/ monitor/ diagnose, or aid in diagnosis, prognosis, and prediction:	This centrifuge is intended to separate human samples, including blood, urine and other bodily fluids.
The specific disorder, condition or risk fact of interest that is intended to be detected, defined, or differentiated	Not applicable. This centrifuge is to prepare samples for downstream in vitro diagnostic procedures and it isn't intended to detect or define any clinical condition.
Automation:	Not applicable. This centrifuge is not an automated instrument.
Qualitative, semi-quantitative or quantitative:	Not applicable. This centrifuge does not provide the testing result.
Type of specimen(s):	Human samples, including blood, urine and other bodily fluids.
Testing population:	Not applicable. This centrifuge is for sample preparation and does not provide tests.
Intended user:	This centrifuge should be operated by laboratory professionals only.
For companion diagnostics, the target population and associated medicinal product(s):	Not applicable. This centrifuge is not a companion diagnostics device.

This unit has been constructed and conforms to the following:

Safety Standards and Directives:

EN/IEC 61010-1 ed. 3.1, 2017

EN/IEC 61010-2-020 ed. 3, 2016

EN/IEC 61010-2-101 ed.3, 2018

UL Std. 61010-1 ed. 3, 2019

UL Std. 61010-2-020 ed. 3, 2016

CAN/CSA C22.2 No. 61010-1-12 (R2017) CAN/CSA C22.2 No. 61010-2-020 (R2017)

IVDF 2017/746 (In-Vitro Diagnostic Medical Devices Regulation)

2014/35/EU (Low Voltage Directive)

EMC Standards:

IEC/EN 61326-1: 2020

IEC/EN 61326-2-6: 2020

FCC Part 15, Subpart B: 2015

ICES-003, Issue 7 2012/19/EU (WEEE)

2015/863/EU (RoHS)

Signed:

Gary Kamees

Title: Vice President Product Development/Manufacturing Location:

VernonHills, IL

Date of Issue: June 2023



Note: Changes or modifications to the product not expressly approved by the manufacturer could void the user's authority to operate the equipment.