

Declaration of Conformity

Manufacturer: Harvard Apparatus, a Division of Harvard Bioscience¹
Address: 84 October Hill Road, Holliston, Massachusetts 01746-1388, USA

We herewith declare that the following products:

Product Name: Pulsatile Blood Pumps
Models: 55-1838, 52-9552, 55-3321, 55-3305

Are in conformity of the following applicable European regulations and directives:

2014/35/EU	Low Voltage directive (LVD)
2014/30/EU	Electromagnetic Compatibility Directive (EMC)
2011/65/EU	Restriction on the use of certain hazardous substances directive (RoHS) ²
2012/19/EU	Waste electrical and electronic equipment directive (WEEE) ²

Standards used to demonstrate conformity include:

EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control and laboratory use, General Requirements
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use –EMC requirements ³
EN 50581:2012	Assessment of products with respect to RoHS

¹Harvard Bioscience holds an ISO 9001:2008 certificate BSI FM 629138 for its Quality Management System

²Classified as belonging to equipment categories 8 or 9

³Classified and tested as class B equipment in accordance with CISPR 11 definition in a basic electromagnetic environment. This equipment has also been tested and found to comply with the limits for a class A digital device, pursuant to CFR Title 47 part 15 of the FCC rules.

I, the undersigned, hereby declare that the equipment specified is in conformity with the relevant harmonised Union legislation. Signed for and on behalf of Harvard Apparatus at Holliston, USA



Signed:

A handwritten signature in black ink, appearing to read 'Mark Davis'.

Date:

June 16, 2017

Mark Davis
Harvard Bioscience, Director of
Engineering