Declaration of Conformity for CE/UKCA Marking

Machinery Directive 2006/42/EU (Safety) / Machine Regulation SI 2008 Nr. 1597
Low Voltage Directive 2014/35/EU / Low Voltage Regulation SI 2016 No. 1101
EMC Directive 2014/30/EU / EMC Regulation SI 2016 Nr. 1091
RoHS Directive 2011/65/EU / RoHS Regulation SI 2021 Nr. 3032

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We herewith declare that the ***PuraLev® PMS-i2048SU*** *mixer system*, in its various configurations as listed below, is in conformity with the above mentioned *European Directives* and *UK Statutory Instruments*. The various configurations of the mixer system are thought to be used in hydraulic circuits of industrial production equipment of Life Science (Biotech, Pharmaceuticals) applications.

Part Name	***Description***
LPI-2000.x	Single-use mixer impellers made in biocompatible propylene.
IPD-2048.x	Mixer drivers with 48 VDC input voltage with various housing coatings, cable materials, connector types, and interfacing options.
Accessories	Driver adaptor and interconnect cables of various length, and others.

Machinery Directive 2006/42/EU – Machinery Regulation SI 2008 Nr. 1597:

The machinery directive/regulation essentially has been followed by a risk analysis, according mitigation actions and a user manual for safe operation. For the design and testing the following standards are used as a guideline:

ISO 12100 : 2010 Safety for machinery – Principles for risk assessments: Used for system risk analysis.
DIN EN 60529 : 2014 Degree of protection provided by enclosure (IP code)

Low Voltage Directive 2014/35/EU – Low Voltage Regulation SI 2016 No. 1101:

The low voltage directive/regulation essentially has been followed by a risk analysis, electrical safety testing and a user manual for safe electrical operation. For the design and testing the following standards are used as a guideline:

EN IEC 61010-1 : 2012 Safety requirements for electrical equipment: Tested by certified 3rd party laboratory.
EN IEC 61010-2-051 : 2019 Safety requirements for electrical equipment – Particular requirements for laboratory equipment for mixing and stirring: Tested by certified 3rd party laboratory.

EMC Directive 2014/30/EU - EMC Regulation SI 2016 Nr. 1091:

The following standards of the EMC directive/regulation have been tested and confirmed at a certified laboratory:

EN IEC 61000-6-2 : 2019 Generic standards – Immunity for industrial environments
EN IEC 61000-6-4 : 2019 Generic standards – Emission standard for industrial environments

RoHS Directive 2011/65/EU – RoHS Regulation SI 2012 Nr. 3032:
The above parts are in conformity with the RoHS directive/regulation.

Start of CE marking:	28-Jan-2021
Last update:	06-Dec-2024
Place of issue:	Zurich, Switzerland

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