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 Nr. 1101
EMC Directive 2014/30/EU / EMC Regulation SI 2016 Nr. 1091

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We herewith declare that the ***PuraLev® PMS-10KSU*** *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-10K.x	Single-use mixer impellers made in biocompatible polypropylene.
LPM-10K.x	Bearingless motors: *LPM-10K.x* (x = various configurations, e.g. motor cable, connectors, coating options)
LPC-4000S.x	Controller with 200 - 240V AC inputs *LPC-4000S.x* (x = various interfacing options, galvanic separated from high-voltage side)
Accessories	Motor controller 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:

ISO12100	Safety for machinery – principles for risk assessments: used for system risk analysis.
IEC/EN 60529	Degree of protection provided by enclosure (IP code)

Low Voltage Directive 2014/35/EU – Low Voltage Regulation SI 2016 Nr. 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:

IEC/EN 61010-1	Safety requirements for electrical equipment: tested by certified 3rd party laboratory.
ISO12100	Safety for machinery – principles for risk assessments: used for system risk analysis.

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

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

EN61000-6-2	Generic standards, Immunity for industrial environments
EN61000-6-4	Generic standards, Emission standard for industrial environments

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