

Declaration of Conformity for CE/UKCA Marking



Machinery Directive 2006/42/EU (Safety) / Machine Regulation SI 2008 Nr. 1597
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-i30SU** 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-30.x	Single-use mixer impellers made in biocompatible propylene.
IPD-30.x	Mixer drivers for 24 VDC supply with various housing coatings, cable materials and interfaces.

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 : 2010 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:

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.

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