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

Manufacturer: Levitronix GmbH
Bändliweg 30
CH-8048 Zurich, Switzerland
Tel.: +41-44-974 40 00

We herewith declare that the ***Centrifugal Pump System Family PuraLev® 2000MU(.S)***, in its configurations as listed below is in conformity with the above mentioned *European Directives* and UK *Statutory Instruments*. The pump system is thought to be used in hydraulic circuits of production equipment of Life Science markets like Biotech and Pharmaceuticals.

Part Name	***Description***	
LPP-2000.x	Pump casing configurations consisting of variations concerning fittings, O-Rings, biocompatible wet materials and performance. See separate declaration for biocompatibility.	and impellers with various biocompatible materials and performance variations. See separate declarant. for biocompatibility.
LPM-2000.x	Bearingless motors: *LPM-2000.x* (x = various cable, connector and coating options)	
LPC-2000(S).x	Controllers with 200 - 240V AC inputs *LPC-2000(S).x* (x = various interfacing options, galvanic separated from high-voltage side)	
Accessories	Motor controller adaptor cables of various length, air cooling module 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:

EN809	Pumps for Fluids: basic requirements are followed.
EN12162	Procedure for hydrostatic pressure testing in fluid pumps: used for max. pressure testing of pump head.
ISO12100	Safety for machinery – principles for risk assessments: used for system risk analysis.

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

Start of CE-Marking:	2012-Mar-15	Place of issue:	Zurich, Switzerland
Last Update:	2025-Oct-06		

Levitronix GmbH
Dr. N. Barletta / CTO

Levitronix GmbH
Th. Eberle / Quality Manager