

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® Console LCO-2000**, in its configurations as listed below is in conformity with the above mentioned *European Directives* and *UK Statutory Instruments*. The console is thought to be used in laboratory and industrial production environment of Life Science markets like Biotech and Pharmaceuticals.

Part Name	Description
LCO-2000.x-yy	LCO-2000.x-yy with x = various hardware configuration options and yy = various firmware options. Consoles with 1 x 200 – 240 / 2kW, 50/60 Hz or 3 x 200 – 240 / 2.1 kW, 50/60 Hz supply input. As critical main components the console contains a NRTL certified LPC-2000 motor controller and NRTL certified circuit breakers and contactors.
LCO-i100.x-yy	LCO-i100.x-yy with x = various hardware configuration options and yy = various firmware options. Console (24 V) as control and display unit.
Motors	Compatible NRTL certified LPM-2000.x motors of the PuraLev® 2000SU/MU pump system.
Pump Heads	Single-Use DCP-2000.x and Multi-Use CP-4.x pump heads of the PuraLev® 2000SU/MU pump system.
Flow Sensors	Clamp-on flow sensors of the LEVIFLOW® LFSC-D and LFSC-iX Series. Single-Use sensors of the LEVIFLOW® LFS-SU Series.
Accessories	Various signal adaptor cables for LEVIFLOW® flow sensors.

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 at 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:

IEC 61800-3 : 2017 Adjustable speed electrical power systems – Part 3: EMC requirements and specific test methods
 CISPR 11 : 2015-06 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement

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