

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® Flex Controller**, in its configurations as listed below, is in conformity with the above-mentioned *European Directives* and *UK Statutory Instruments*. The **PuraLev® Flex Controller** unit is thought to be used in laboratory and industrial production environment of life science markets like biotech and pharmaceuticals.

Part Name	Description
LCO-Flex	LCO-FLEX-x.y-zz with x and y = various hardware configuration options and zz = various firmware options. Control units with 24 VDC for up to 160 W supply input. <i>Note: The standard specified AC/DC power supplies are commercially available NRTL certified components.</i>

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	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
UL62368-1	Fulfilled by the specified standard commercially available AC/DC powers supplies.
ISO 12100	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 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements
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