

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

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We herewith declare that the **Centrifugal Pump System PuraLev® 600SU**, in its various 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 single-use hydraulic circuits of production equipment of Life Science markets like Biotech and Pharmaceuticals.

Part Name	Description
DCP-600.x	Single-Use pump head with Biocompatible materials and variations of things like fittings. See separate declaration for biocompatibility.
LPM-600.x	Bearingless motors: LPM-600.x (x = various cable, connector and coating options)
LPC-600.x-xx	Controllers with 48V DC / 600 W supply inputs: LPC-600.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.

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

Test Laboratory: Hochschule für Technik Zurich
 EMV Labor, Technoparkstr. 1
 CH-8005 Zurich, Switzerland

Swiss certification number = STS 404

Start of CE-Marking:	2012-Sep-01	Place of issue:	Zurich, Switzerland
Last Update:	2022-Sep-27		
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