

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 Family PuraLev® 200SU**, 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 single use hydraulic circuits of production equipment of Life Science markets like Biotech and Pharmaceuticals.

Part Name	Description
DCP-200.x (Single-Use Pump Head)	Pump casing configurations consisting of variations concerning fittings, biocompatible wet materials and performance. See separate declaration for biocompatibility. and impellers with various biocompatible materials and performance variations. See separate declarant. for biocompatibility.
BSM-1.x	Bearingless motors: BSM-1.x (x = various cable, connector and coating options)
LPC-200.x	Controllers with 24-48 VDC input: LPC-200.x (x = various interfacing options)
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: BYTICS AG
 (former „Hochschule für Technik Zürich)
 EMV Labor, Technoparkstr. 1
 CH-8005 Zurich, Switzerland

Swiss certification number = STS 404

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