

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
Radio Eq. Directive 2014/53/EU / Radio Eq. Regulation SI 2017 Nr. 1206
RoHS Directive 2011/65/EU / RoHS Regulation SI 2021 Nr. 3032

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We herewith declare that the **Centrifugal Pump System Family FSP-i30SU**, 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 Life Science markets like Biotech and Pharmaceuticals.

Part Name	Description
DGP-30.4	Single-use pump heads with 12 mm barb fittings and PC housing with EPDM O-ring.
IPD-30.10	Battery powered pump driver.

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:

<i>DIN EN 809 : 2012</i>	Pumps for fluids, basic requirements are followed.
<i>DIN EN 12162 : 2010</i>	Procedure for hydrostatic pressure testing in fluid pumps, used for max. pressure testing of pump head.
<i>ISO 12100 : 2010</i>	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 have been tested and confirmed at a certified laboratory:

<i>EN IEC 61000-6-2 : 2019</i>	Generic standards – Immunity for industrial environments
<i>EN IEC 61000-6-3 : 2019</i>	Generic standards – Emission standard for residential, commercial and light-industrial environments

Radio Equipment Directive 2014/53/EU - Radio Equipment Regulation SI 2017 Nr. 1206

The following standard/regulation of the radio equipment directive has been tested and confirmed at a certified laboratory:

<i>ETSI EN 303417 : 2017</i>	Wireless power transmission systems, using technologies other than radio frequency beam
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RoHS Directive 2011/65/EU – RoHS Regulation SI 2012 Nr. 3032:

The above parts are in conformity with the RoHS directive/regulation.

Start of CE marking:	11-Feb-2019
Last update:	06-Dec-2024
Place of issue:	Zurich, Switzerland
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