

CE Declaration of conformity (CE DoC)

Manufacturer : Kinova® Robotics- SRN CA-MF-000003231
 4333 Boulevard de la Grande-Allée,
 Boisbriand, QC J7H 1M7, Canada
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Kinova® Robotics declares under its sole responsibility that the following product:

Product Name	Jaco®
Product Model Number	KR MJ2 0001
Product class	Class I medical device
Product Basic - UDI	628678941PJ00900006B5
Following accessories may be included	(1) Joystick - AO 0000 0001 (2) Lift Arm - KR8600 (3) OLED Display - PD 0508 0001 (4) Control Box – DB9 Kit PC 0000 0003-DB9 (5) Control Box – Rnet Kit PC 0000 0003-Rnet

Complies with the following Regulations and/or Directives:

2017/745/EU	Medical device Regulation
2011/65/EU RoHS	Restriction Of Hazardous Substances (in electrical and electronic equipment)
2014/30/EU EMC	Electromagnetic Compatibility
2012/19/EU WEEE	Waste Electronic and Electrical Equipment

Complies with the following Standards

ISO 13485: 2016	Medical devices Quality management systems Requirements for regulatory purposes
ISO 14971: 2019	Medical devices - Application of risk management to medical devices
EN 60601-1-2 (2014)	Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances
EN 60601-1 (2005) A1(2012)	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
EN 60601-1-11 (2015)	Medical electrical equipment-Part 1-11: General requirements for basic safety and essential performance-Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Contact manufacturer's EU representative:

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Contact manufacturer's KS Swiss representative:

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Signature



Electronically signed by: Keven Fréchette
 Reason: I have reviewed and I approve the content of this document.
 Date: Nov 28, 2023 15:27 EST

Keven Fréchette
 Manager, Quality Assurance

Boisbriand, Canada

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Local contact for regulatory topics only

Please direct all question regarding regulatory compliance to: garegulatory@kinova.ca