

## Declaration of Conformity

**Manufacturer:****KEYMED (MEDICAL AND INDUSTRIAL EQUIPMENT) LTD.**KeyMed House  
Stock Road  
Southend-on-Sea  
Essex SS2 5QH  
United Kingdom**Single Registration Number (SRN)**

GB-MF-000035162

**EU authorized representative (EC rep)**

Olympus Europa SE &amp; Co. KG Wendenstr.14-20, 20097, Hamburg, Germany

**EC Rep Single Registration Number (SRN)**

DE-AR-000006774

**Swiss authorized representative (CH Rep)**

Olympus Schweiz AG, Richtiring 30, 8304 Wallisellen, Switzerland

**Product Designation:**

OFP-2 Flushing Pump System

**This declaration was made under the sole responsibility of the manufacturer.****The stated products comply with the requirements of following European Directives/Regulations and UK Regulations:****The declaration is based on:****2017/745 (Annex IX, as applicable)**

Medical Device Regulation (EU)

**2002 No. 618 (as per 93/42/EEC as amended by Directive 2007/47/EC [Annex II, excluding Section 4], as modified by Part 2 of Schedule 2A to the UK MDR 2002)**

Medical Device Regulations 2002 (UK)

(excluding MAJ-1651, MAJ-1652, MAJ-2220, MAJ-2221, MAJ-2222, MAJ-2223)

**2011/65/EU** and the commission delegated directive 2015/863

Restriction of Hazardous Substances (RoHS) Directive

**2012 No. 3032**

Restriction of Hazardous Substances (RoHS) Regulation (UK)

**1907/2006**

EU REACH (Registration Evaluation and Authorization of Chemicals)

**2019 No. 758**

UK REACH (Registration Evaluation and Authorisation of Chemicals)

**2017/821**

Use of Conflict Minerals

**Notified body**

Excluding class I medical devices which are non-sterile and without a measuring function

**BSI Group**Say Building  
John M. Keynesplein 9  
1066 EP Amsterdam  
Netherlands

**UK approved body**

**BSI UK**

Kitemark Court  
Davy Avenue, Knowlhill  
Milton Keynes  
MK5 8PP

**UK  
CA** 0086

**Place, Issue, Date:**

Southend-on-Sea, Issue 16, 12/11/2023

**Signature:**



Shaleenah Ramjan  
General Manager RA, Deputy Person Responsible for Regulatory Compliance  
(PRRC)

**The Declaration of Conformity is valid for the following articles:**

Product designation	GMDN	Article (REF) No. / Article name	Beginning with Serial No. / Lot	UDI-DI	Basic UDI-DI	Classification
Flushing Pump	63646	Part K10001143 OFP-2 (EU)	EU MDR: From MDR 737637 CE certificate issue	150197780 03214	5019778 MF001QW	<b>EU MDR</b> Class IIa (Annex VIII / Rule 12)
		Part K10001144 OFP-2 (UK)	EU MDR: From MDR 737637 CE certificate issue	150197780 03221		<b>EU MDR</b> Class IIa (Annex VIII / Rule 12)
			UK MDR: 22135086			<b>UK MDR</b> Class IIa (Annex IX / Rule 11)
		K10001141 OFP-2 (US)	EU MDR: From MDR 737637 CE certificate issue	15019778 003191	N/A	FDA Class II
		K10001142 OFP-2 (JP)	EU MDR: From MDR 737637 CE certificate issue	15019778 003207		PMDA Class II
		K10001145 OFP-2 (ROW)	EU MDR: From MDR 737637 CE certificate issue	15019778 003238		<b>EU MDR</b> Class IIa (Annex VIII / Rule 12)

Instrument Channel Adaptor (10)	60758	Part K10016091 MAJ-1606	EU MDR: From MDR 737637 CE certificate issue UK MDR: 20278185	150197780 03528	5019778MF00 10029V	<b>EU MDR</b> Class IIa (Annex VIII / Rule 2)  <b>UK MDR</b> (Annex IX / Rule 2)
Instrument Channel Adaptor (100)		Part K10007072 MAJ-1606	EU MDR: From MDR 737637 CE certificate issue UK MDR: 20278187	150197780 03351		
Instrument Channel Adaptor (10) CN		Part K10037379 MAJ-1606	EU MDR: From MDR 737637 CE certificate issue	150197780 08561		
Instrument Channel Water Tube (10)	16779	Part K10016136 MAJ-1607	EU MDR: From MDR 737637 CE certificate issue UK MDR: 214802	150197780 03535	5019778MF00 10039X	
Instrument Channel Water Tube (50)		Part K10001146 MAJ-1607	EU MDR: From MDR 737637 CE certificate issue UK MDR: 214803	150197780 03368		
Instrument Channel Water Tube (10) CN		Part K10037383 MAJ-1607	EU MDR: From MDR 737637 CE certificate issue	150197780 08578		

Auxiliary Channel Water Tube (10)	64108	Part K10016135 MAJ-1608	EU MDR: From MDR 737637 CE certificate issue UK MDR: 213803	150197780 03542	5019778MF00 10049Z	
Auxiliary Channel Water Tube (10) CN	64108	Part K10037381 MAJ-1608	EU MDR: From MDR 737637 CE certificate issue	150197780 08585	5019778MF00 10049Z	<b>EU MDR</b> Class IIa (Annex VIII / Rule 2)  <b>UK MDR</b> (Annex IX / Rule 2)
Auxiliary Channel Water Tube (50)		Part K10001147 MAJ-1608	EU MDR: From MDR 737637 CE certificate issue UK MDR: 213703	150197780 03375		
Auxiliary Channel Water Tube Set (100)		Part K10023086 MAJ-1651	EU MDR: From MDR 737637 CE certificate issue UK MDR: Pending	150197780 04716	5019778MF00 1005A3	
Auxiliary Channel Adaptor (100)	60758	Part K10020736 MAJ-1652	EU MDR: From MDR 737637 CE certificate issue UK MDR: Pending	150197780 04709	5019778MF00 1006A5	
Accessory Port Tube with Bottle Cap (10)	46102	Part K10026641 MAJ-1681	EU MDR: From MDR 737637 CE certificate issue UK MDR: 20273267	150197780 05072	5019778MF00 1007A7	

Accessory Port Tube with Bottle Cap (10) CN		Part K10037385 MAJ-1681	EU MDR: From MDR 737637 CE certificate issue	150197780 08592		
Accessory Port Tube with Saline Spike (10)		Part K10026686 MAJ-1682	EU MDR: From MDR 737637 CE certificate issue UK MDR: 20271474	150197780 05089		
Accessory Port Tube with Saline Spike (10) CN		Part K10037386 MAJ-1682	EU MDR: From MDR 737637 CE certificate issue	150197780 08608		
Irrigation Tubing with CO <sub>2</sub> (10)	60738	Part K10035002 MAJ-2207	EU MDR: From MDR 737637 CE certificate issue UK MDR: 20269754	150197780 07700	5019778MF00 1008A9	<b>EU MDR</b> Class IIa (Annex VIII / Rule 2)  <b>UK MDR</b> (Annex IX / Rule 2)
Irrigation Tubing with CO <sub>2</sub> (10)		Part K10035003 MAJ-2208	EU MDR: From MDR 737637 CE certificate issue UK MDR: 20269740	150197780 07717		
Irrigation Tubing with Air (10)		Part K10035004 MAJ-2209	EU MDR: From MDR 737637 CE certificate issue UK MDR: 20269767	150197780 07724		

Irrigation Tubing with Air (10)		Part K10035005 MAJ-2210	EU MDR: From MDR 737637 CE certificate issue UK MDR: 20269771	150197780 07731		
Insufflation Tubing with CO <sub>2</sub> (10)		Part K10037161 MAJ-2220	EU MDR: From MDR 737637 CE certificate issue UK MDR: Pending	150197780 08516	5019778MF00 1009AB	
Insufflation Tubing with CO <sub>2</sub> (10)		Part K10037162 MAJ-2221	EU MDR: From MDR 737637 CE certificate issue UK MDR: Pending	150197780 08523		
Insufflation Tubing with Air (10)		Part K10037163 MAJ-2222	EU MDR: From MDR 737637 CE certificate issue UK MDR: Pending	150197780 08530		
Insufflation Tubing with Air (10)	60738	Part K10037164 MAJ-2223	EU MDR: From MDR 737637 CE certificate issue UK MDR: Pending	150197780 08547	5019778MF00 1009AB	

### Intended Purpose

The Olympus OFP-2 Flushing Pump is a peristaltic pump intended to supply fluid to compatible Olympus endoscopes or endotherapy devices for irrigation of the gastric and colonic mucosa during endoscopic or endotherapeutic procedures, allowing improved visualisation, diagnosis and treatment.

The pump can also assist in the use of transendoscopic ultrasound probes by rapidly filling the organ to be examined.

**Applied standards, common specifications and guidance that demonstrate compliance to the regulations:**

Standard	Standard Description	Applicable to
BS EN ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	All products within DoC
BS EN ISO 14971	Risk Management for Medical Devices	All products within DoC
BS EN 62366-1	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices	All products within DoC
BS ISO 20417	Medical devices — Information to be supplied by the manufacturer.	All products within DoC
BS EN ISO 15223-1	Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied	All products within DoC
BS EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	All products within DoC
BS EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	All products within DoC except - OFP-2 flushing pump
BS EN ISO 10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization Residuals	All products within DoC except - OFP-2 flushing pump - MAJ-1603 water container - MAJ-1606 instrument channel adaptor - MAJ-1652 auxiliary channel adaptor
BS EN ISO 10993-10	Biological evaluation of medical devices. Tests for irritation and skin sensitization	All products within DoC except - OFP-2 flushing pump

Standard	Standard Description	Applicable to
EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	<ul style="list-style-type: none"> <li>- MAJ-1681 Accessory port tube with bottle cap</li> <li>- MAJ-1682 Accessory port tube with saline spike</li> </ul>
ISO 10993-18	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	All products within DoC
BS EN 60601-1	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance	OFP-2 flushing pump
BS EN 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests	OFP-2 flushing pump
IEC 61000-3-2	EMC Limits for harmonic current emissions (equipment in-put current $\leq 16$ A per phase)	OFP-2 flushing pump
IEC 61000-3-3	EMC Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leq 16$ A per phase and not subject to conditional connection	OFP-2 flushing pump
BS EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging System	All products within DoC except <ul style="list-style-type: none"> <li>- OFP-2 flushing pump</li> <li>- MAJ-1603 water container</li> </ul>
BS EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	All products within DoC except <ul style="list-style-type: none"> <li>- OFP-2 flushing pump</li> <li>- MAJ-1603 water container</li> </ul>

Standard	Standard Description	Applicable to
BS EN 556-1	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices	All products within DoC except - OFP-2 flushing pump - MAJ-1603 water container
BS EN ISO 11137-1	Sterilization of health care products – Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	- MAJ-1606 Instrument channel adaptor - MAJ-1652 Auxilliary channel adaptor
BS EN ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	All products within DoC except - OFP-2 flushing pump - MAJ-1603 water container
BS EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	All products within DoC except - OFP-2 flushing pump - MAJ-1603 water container
MEDDEV 2.7/1	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC	All products within DoC
BS EN 62304	Medical device software. Software life-cycle processes	OFP-2 flushing pump

Standard	Standard Description	Applicable to
BS EN ISO 11135	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	All products within DoC except <ul style="list-style-type: none"> <li>- OFP-2, OFP-3 and OFP-3 PLUS flushing pump</li> <li>- MAJ-1603 water container</li> <li>- MAJ-1606 Instrument channel adaptor</li> <li>- MAJ-1652 Auxilliary channel adaptor</li> </ul>