EC – 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):	N/A
Product designation:	**OFP-2 Flushing Pump**
Article (REF) No. / Article name:	**Please refer to Attachment 1**
Beginning with Serial No. / Lot:	**Please refer to Attachment 1**
Product classification:	**Please refer to Attachment 1**

This declaration was made under the sole responsibility of the manufacturer.

The stated product complies with the requirements of following European Directives:

The declaration is based on:	**93/42/EEC** as amended by Directive 2007/47/EC	**Medical Device Directive**
	2011/65/EU	**RoHS Directive**
EU Representative (EC Rep)	**Olympus Europa SE & Co. KG** Wendenstr.14-20, 20097, Hamburg, Germany	
Notified body for products of class IIa to IIb:	**BSI Group** Say Building John M. Keynesplein 9 1066 EP Amsterdam Netherlands	CE 2797

Place, Issue, Date: Southend-on-Sea, Issue 1, 18.12.2020

Signature:

Regina Galera
RA/QA Manager and Deputy Person Responsible for Regulatory Compliance (PRRC)

ATTACHMENT 1

The EC-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)	All	15019778003214	5019778 MF001QW	Class IIa (Annex VIII / Rule 11)
		Part K10001144 OFP-2 (UK)	All	15019778003221		
		K10001141 OFP-2 (US)	All	15019778003191	N/A	FDA Class II
		K10001142 OFP-2 (JP)	All	15019778003207		PMDA Class II
		K10001145 OFP-2 (ROW)	All	15019778003238		Class IIa (Annex VIII / Rule 11)
Water Container (2L) (3)		Part K10007071 MAJ-1603	All	15019778003344	5019778 MF001QW	Class I (Annex VIII, Rule 2)
Instrument Channel Adaptor (10)	60757	Part K10016091 MAJ-1606	All	15019778003528		Class IIa (Annex VIII / Rule 2)
Instrument Channel Adaptor (100)		Part K10007072 MAJ-1606	All	15019778003351		

Instrument Channel Water Tube (10)	63646	Part K10016136 MAJ-1607	All	15019778003535	5019778 MF001QW	.
Instrument Channel Water Tube (50)	63646	Part K10001146 MAJ-1607	All	15019778003368		Class IIa (Annex VIII/ Rule 2)
Auxiliary Channel Water Tube (10)		Part K10016135 MAJ-1608	All	15019778003542		
Auxiliary Channel Water Tube (50)		Part K10001147 MAJ-1608	All	15019778003375		
Auxiliary Channel Water Tube Set (100)		Part K10023086 MAJ-1651	All	15019778004716		
Auxiliary Channel Adaptor (100)		Part K10020736 MAJ-1652	All	15019778004709		
Accessory Port Tube with Bottle Cap (10)		Part K10026641 MAJ-1681	All	15019778005072		
Accessory Port Tube with Saline Spike (10)		Part K10026686 MAJ-1682	All	15019778005089		
Hybrid Tube Set - Irrigation Tubing with CO_2 (10)		Part K10035002 MAJ-2207	All	15019778007700		
Hybrid Tube Set - Irrigation Tubing with CO_2 (10)		Part K10035003 MAJ-2208	All	15019778007717		
Hybrid Tube Set - Irrigation Tubing with Air (10)		Part K10035004 MAJ-2209	All	15019778007724		
Hybrid Tube Set - Irrigation Tubing with Air (10)		Part K10035005 MAJ-2210	All	15019778007731		

Applied Standards

ISO 14971:2012	Risk management for medical devices
ISO 13485:2016	Medical Devices – Quality Management Systems – requirements for regulatory purposes
IEC 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices
IEC 60601-1:2006+A12:2014 (Edition 3.1)	Medical electrical equipment: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 (4th Edition)	Electromagnetic disturbances. Requirements and tests
IEC 60601-2-2:2002+AMD:2018	Electromagnetic compatibility (EMC) - Environment - Compatibility levels for low-frequency conducted disturbances and signalling in public low-voltage power supply systems
IEC 61000-3-2:2014	EMC - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
IEC 61000-3-3:2013	EMC - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
ISO 10993-1:October 2009	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
ISO 11137-1:2015	Method 1 Sterility Assurance Validation - Irradiation
ISO 11135-1:2014	Sterilization of health care products. Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11607-1:2017	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

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.