


Declaration of Conformity

Manufacturer:	KEYMED (MEDICAL AND INDUSTRIAL EQUIPMENT) LTD. KeyMed House Stock Road Southend-on-Sea Essex SS2 5QH United Kingdom	
EU authorized representative (EC rep)	Olympus Europa SE & Co. KG Wendenstr.14-20, 20097, Hamburg, Germany	
Swiss authorized representative (CH Rep)	Olympus Schweiz AG, Richtiring 30, 8304 Wallisellen, Switzerland	
Product Designation:	WM-NP3 Workstation	
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	Medical Device Regulation (EU)
	2002 No. 618	UK Medical Device Regulations 2002
	2014/30/EU	Electromagnetic Compatibility Directive (EU)
	2016 No. 1091	Electromagnetic Compatibility Regulations (UK)
	2014/35/EU	Low Voltage Directive
	2016 No. 1101	The Electrical Equipment Safety Regulations 2016 (UK)
	2011/65/EU and the commission delegated directive 2015/863	RoHS Directive
	2012 No. 3032	RoHS Regulation (UK)
	1907/2006	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	N/A for Class I devices	
		

UK approved body

N/A for Class I devices



Place, Issue, Date:

Southend-on-Sea, Issue 10, 20/09/2023

Signature:

A handwritten signature in black ink, appearing to read 'SR', written over a horizontal line.

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

The Declaration of Conformity is valid for the following articles:

Table 1

Product designation	GMDN	Article (REF) No. / Article name	Beginning with Serial No. / Lot	UDI-DI	Basic UDI-DI	Classification
WORKSTATION	35124	WM-NP3 Basic UK (K10029987)	All	15019778007762	5019778 MF003R2	EU MDR Class I (Annex VIII, Rule 13)
			22121663			UK MDR Class I (Annex IX, Rule 1)
WORKSTATION	35124	WM-NP3 GI Set UK (K10035364)	All	15019778007816	5019778 MF003R2	EU MDR Class I (Annex VIII, Rule 13)
			22121667			UK MDR Class I (Annex IX, Rule 1)
WORKSTATION	35124	WM-NP3 Basic EU (K10035360)	All	15019778007779	5019778 MF003R2	EU MDR Class I (Annex VIII, Rule 13)
WORKSTATION	35124	WM-NP3 Basic US (K10035361)	All	15019778007786	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 Basic JP (K10035362)	All	15019778007793	5019778 MF003R2	

Product designation	GMDN	Article (REF) No. / Article name	Beginning with Serial No. / Lot	UDI-DI	Basic UDI-DI	Classification
WORKSTATION	35124	WM-NP3 Basic ROW (K10035363)	All	15019778007809	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 Basic US 15A (K10037157)	All	15019778008462	5019778 MF003R2	EU MDR Class I (Annex VIII, Rule 13)
WORKSTATION	35124	WM-NP3 GI Set EU (K10035365)	All	15019778007823	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 GI Set US (K10035366)	All	15019778007830	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 GI Set JP (K10035367)	All	15019778007847	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 GI Set ROW (K10035368)	All	15019778007854	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 GI Set US 15A (K10037158)	All	15019778008479	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 URO Set EU (K10035370)	All	15019778007878	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 URO Set US (K10035371)	All	15019778007885	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 URO Set ROW (K10035373)	All	15019778007908	5019778 MF003R2	
WORKSTATION	35124	WM-NP3 US 15A UR (K10037159)	All	15019778008486	5019778 MF003R2	

The following components can be used with the articles in the Table 1 but are not CE marked:

Table 2

Product designation	Article (REF) No. / Article name	UDI-DI	Basic UDI-DI
WORKSTATION COMPONENT	MAJ-150 Adaptor cable (K7505088)	15019778005232	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1635 EUS connector holder (K10011159)	15019778003412	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1639 Single CO2 holder (up to Ø140mm) (K10021041)	15019778003658	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1642 IV Pole (K10016952)	15019778003801	5019778MF003R2

Product designation	Article (REF) No. / Article name	UDI-DI	Basic UDI-DI
WORKSTATION COMPONENT	MAJ-1642 IV Pole (K10037174)	15019778008509	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1650 Single CO2 holder (Ø140mm to Ø205mm) (K10021042)	15019778003641	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1653 Double CO2 holder (K10021043)	15019778003634	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1654 Equipotential terminal strip (K10021352)	15019778003818	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1657 Keyboard arm - side mounted (K10021791)	15019778003979	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1661 LCD Adjustable Arm (K10021795)	15019778004471	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1663 EUS Arm mount kit (K10021797)	15019778004020	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1665 Camera head holder (K10036681)	15019778008226	5019778MF003R2
WORKSTATION COMPONENT	MAJ-1685 IV Bag Hanger (K10027568)	150197780074796	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2145 ENT Scope Hanger (K10026497)	15019778007168	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2146 Sliding Keyboard Tray (K10027573)	15019778006680	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2149 Dual Monitor Arm (K10027575)	15019778004037	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2151 System Control Arm (K10028132)	15019778008066	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2154 Consumable Stowage Holder (K10030423)	15019778008004	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2158 Suction Jar Holder (K10028139)	15019778007984	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2159 Scope Pole Kit (K10028140)	15019778007991	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2160 Irrigation Tube Holder (K10028141)	15019778008011	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2165 Drawer Unit (K10030178)	15019778008028	5019778MF003R2

Product designation	Article (REF) No. / Article name	UDI-DI	Basic UDI-DI
WORKSTATION COMPONENT	MAJ-2166 Sterile Water Holder (K10030036)	15019778008035	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2167 Nurses Control Arm (K10030210)	15019778008073	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2173 Side Shelf (K10030389)	15019778008042	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2211 Side Handles (K10035108)	15019778008059	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2216 LCD Monitor Arm 6.5-12Kg (K10035789)	15019778008080	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2216 LCD Monitor Arm 6.5-12Kg (K10036256)	15019778009117	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2217 LCD Monitor Arm 12-14Kg (K10035790)	15019778008097	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2155 WM-T3 Transformer 100V (K10028136)	15019778009124	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2156 WM-T3 Transformer 110-120V (K10028137)	15019778009131	5019778MF003R2
WORKSTATION COMPONENT	MAJ-2156-15A WM-T3 Transformer 110-120V (K10037151)	15019778008493	5019778MF003R2

The following components can be used with the articles listed in Table 1 and are CE / UKCA marked in accordance with EU and UK versions of RoHS, LVD and EMC – but not the EU MDR 2017/745 or UK MDR 2002 (No. 618):

Table 3

WORKSTATION COMPONENT	MAJ-2157 WM-T3 Transformer 220-240V (K10028138)	15019778009148	5019778MF003R2
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Intended purpose

The WM-NP3 workstation is intended to assist endoscopic procedures using Olympus medical devices and their accessories within medical facilities by providing a stable mains power supply and a platform for the efficient use and handling of the devices during endoscopic diagnostic and therapeutic procedures. The WM-NP3 workstation can also allow visualisation during the procedure when connected to a monitor.

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

BS EN ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
BS EN ISO 14971	Medical Devices – Application of Risk Management to Medical Devices
BS EN 60601-1	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
BS EN 62366-1	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
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
MEDDEV 2.7/1	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
BS EN 50419	Marking of Electrical and Electronic Equipment in Accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
BS EN ISO 2234	Packaging – Complete, filled Transport Packages and Unit Loads – Stacking Tests using a Static Load
BS ISO 20417	Medical devices — Information to be supplied by the manufacturer.
BS EN ISO 15223-1	Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied