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:	**MAJ-1632 Mouthpiece**
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/Regulations:

The declaration is based on:	**2017/745**	**Medical Device Regulation (EU)**
EU Representative (EC Rep)	**Olympus Europa SE & Co. KG** Wendenstr.14-20, 20097, Hamburg, Germany	
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	CE 2797

Place, Date: Southend-on-Sea, Issue 3, 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
Mouthpiece (single unit)	17595	MAJ-1632 Mouthpiece - Lip Press K10020032	Devices manufactured from 01.10.2020	15019778003597	5019778MF005R6	Class I (Annex VIII, Rule 5)
Mouthpiece (50 piece carton)	17595	MAJ-1632 Mouthpiece - Lip Press K10020960	20241008	15019778003603	5019778MF005R6	Class I (Annex VIII, Rule 5)

Applied standards, common specifications and guidance

EN ISO 13485:2016	Quality Management System
EN ISO 14971:2012	Risk Management for Medical Devices
MEDDEV 2.7/1 Rev 4	Clinical Evaluation
EN 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
ISO10993-1:2009	Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
BS EN ISO 62366-1:2015	Application of usability engineering to medical devices

Intended Purpose

The MAJ-1632 is a single- use mouthpiece intended to hold the patient's mouth open during bronchoscopy and upper gastrointestinal tract endoscopic procedures, allowing facilitated introduction of the endoscopes. The mouthpiece also protects the patient's lips and gums from trauma and the endoscopes from damage due to e.g. biting during the procedure.