

TÜV Rheinland LGA Products GmbH • 51105 Köln

OLYMPUS MEDICAL SYSTEMS CORP.
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Japan

Contact

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Date April 30, 2024

Notified Body Confirmation Letter

Reference. : OMSC_MDR Application 2024-04-16; order # 150294495

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

OLYMPUS MEDICAL SYSTEMS CORP
2951 Ishikawa-cho, Hachioji-shi
Tokyo, 192-8507
Japan
SRN Number: JP-MF-000008016

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Ning N. C. Chang
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
VIDEO SYSTEM CENTER OLYMPUS CV-170	Class IIa	VIDEO SYSTEM CENTER OLYMPUS CV-170	Certificate # HD 60149405 0001 NB # 0197
Single Use Injector NM-600L-0421, NM-600L-0521, NM-600L-0621, NM-600L-0423, NM-600L-0523, NM-600L-0623, NM-600L-0425, NM-600L-0525, NM-600L-0625, NM-610L-0421, NM-610L-0521, NM-610L-0621, NM-610L-0423, NM-610L-0523, NM-610L-0623, NM-610L-0425, NM-610L-0525, NM-610L-0625, NM-610L-0426, NM-610U-0323, NM-610U-0423, NM-610U-0523, NM-610U-0623, NM-610U-1825, NM-610U-0325, NM-610U-0425, NM-610U-0525, NM-610U-0625, NM-610U-1826, NM-610U-0326, NM-610U-0426	Class IIa	Single Use Injector NM-600L-0421	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single Use Biopsy Forceps FB-215U, FB-216U	Class IIa	Single Use Biopsy Forceps FB-215U	Same as above
MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4	Class IIb	MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4	Same as above
WATER CONTAINER MAJ-901	Class IIa	WATER CONTAINER MAJ-901	Same as above
ENDOCAPSULE SOFTWARE 10 MAJ-2188	Class IIa	ENDOCAPSULE SOFTWARE 10 MAJ-2188	Same as above
ENDOCAPSULE SOFTWARE 10 LIGHT MAJ-2189	Class IIa	ENDOCAPSULE SOFTWARE 10 LIGHT MAJ-2189	Same as above
ENDOCAPSULE SOFTWARE 10 UPGRADE PACKAGE MAJ- 2190	Class IIa	ENDOCAPSULE SOFTWARE 10 UPGRADE PACKAGE MAJ-2190	Same as above
Single Use Biopsy Forceps FB-456D (EMDN: R070201)	Class IIa	Single Use Biopsy Forceps FB-456D	Same as above
Single Use Biopsy Forceps FB-456D (EMDN: U090301)	Class IIa	Single Use Biopsy Forceps FB-456D	Same as above
ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120108)	Class IIb	ULTRASONIC BIPOLAR GENERATOR USG-410	Same as above
ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120109)	Class IIb	ULTRASONIC BIPOLAR GENERATOR USG-410	Same as above
URETERO-RENO FIBERSCOPE URF-P7	Class IIa	URETERO-RENO FIBERSCOPE URF-P7	Same as above
URETERO-RENO FIBERSCOPE URF-P7R	Class IIa	URETERO-RENO FIBERSCOPE URF-P7R	Same as above
Luer-Split MAJ-2092	Class IIa	Luer-Split MAJ-2092	Same as above
GASTROINTESTINAL VIDEOSCOPE GIF-1100	Class IIa	GASTROINTESTINAL VIDEOSCOPE GIF-1100	Same as above
COLONOVideoscope CF-HQ1100DL/I	Class IIa	COLONOVideoscope CF-HQ1100DL	Same as above
BRONCHOVIDEO SCOPE BF-1TH1100	Class IIa	BRONCHOVIDEO SCOPE BF-1TH1100	Same as above
SINGLE USE SPLINTING TUBE ST-SB1S	Class IIa	SINGLE USE SPLINTING TUBE ST-SB1S	Same as above
CYSTO-NEPHRO VIDEOSCOPE CYF-VH	Class IIa	CYSTO-NEPHRO VIDEOSCOPE CYF-VH	Same as above
RHINO-LARYNGO VIDEOSCOPE	Class IIa	RHINO-LARYNGO VIDEOSCOPE	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ENF-VT3		ENF-VT3	
BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1200	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1200	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ170	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ170	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-H1200	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-H1200	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-H190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-H190	Same as above
EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F	Class IIa	EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F	Same as above
EVIS LUCERA ELITE BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP290F	Class IIa	EVIS LUCERA ELITE BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP290F	Same as above
EVIS EXERA III BRONCOVIDEOSCOPE OLYMPUS BF-P190	Class IIa	EVIS EXERA III BRONCOVIDEOSCOPE OLYMPUS BF-P190	Same as above
EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-P290	Class IIa	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-P290	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	Same as above
EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UC190F	Class IIa	EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UC190F	Same as above
EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UC290F	Class IIa	EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-UC290F	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190	Same as above
EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-XP290	Class IIa	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-XP290	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	Same as above
COLONOVIDEOSCOPE	Class IIa	COLONOVIDEOSCOPE	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
OLYMPUS CF-EZ1500DI		OLYMPUS CF-EZ1500DI	
COLONOVideoscope OLYMPUS CF-EZ1500DL	Class IIa	COLONOVideoscope OLYMPUS CF-EZ1500DL	Same as above
COLONOVideoscope OLYMPUS CF-H170I	Class IIa	COLONOVideoscope OLYMPUS CF-H170I	Same as above
COLONOVideoscope OLYMPUS CF-H170L	Class IIa	COLONOVideoscope OLYMPUS CF-H170L	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS CF-H185I	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS CF-H185I	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS CF-H185L	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS CF-H185L	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS CF-H190I	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS CF-H190I	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS CF-H190L	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS CF-H190L	Same as above
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-H290ECI	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-H290ECI	Same as above
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-H290I	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-H290I	Same as above
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-H290L	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-H290L	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS CF-HQ190I	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS CF-HQ190I	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS CF-HQ190L	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS CF-HQ190L	Same as above
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-HQ290I	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-HQ290I	Same as above
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-HQ290L	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS CF-HQ290L	Same as above
COLONOVideoscope OLYMPUS CF-XZ1200I	Class IIa	COLONOVideoscope OLYMPUS CF-XZ1200I	Same as above
COLONOVideoscope OLYMPUS CF-XZ1200L	Class IIa	COLONOVideoscope OLYMPUS CF-XZ1200L	Same as above
EVIS EXERA III XENON LIGHT SOURCE OLYMPUS CLV-190	Class IIa	EVIS EXERA III XENON LIGHT SOURCE OLYMPUS CLV-190	Same as above
EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500	Class IIa	EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5	Class IIa	OES CYSTONEPHROFIBERSC OPE OLYMPUS CYF-5	Same as above
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5A	Class IIa	OES CYSTONEPHROFIBERSC OPE OLYMPUS CYF-5A	Same as above
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2	Class IIa	VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2	Same as above
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF- VHA	Class IIa	CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHA	Same as above
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHR	Class IIa	CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHR	Same as above
SINGLE USE POWERSPIRAL TUBE DPST-1	Class IIa	SINGLE USE POWERSPIRAL TUBE DPST-1	Same as above
RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2	Class IIa	RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF- V3	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V3	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4 OLYMPUS ENF-V4	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4 OLYMPUS ENF-V4	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2 OLYMPUS ENF-VH2	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2 OLYMPUS ENF-VH2	Same as above
RHINO- LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP	Class IIa	RHINO- LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP	Same as above
EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT180	Class IIa	EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT180	Same as above
EVIS LUCERA ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT260	Class IIa	EVIS LUCERA ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT260	Same as above
EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF- UE190	Class IIa	EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190	Same as above

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EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF- UE290	Class IIa	EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE290	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF- 1TH190	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190	Same as above
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500	Same as above
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H170	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H170	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF- H185	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H185	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF- H190	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF- H190N	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190N	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF- H290	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF- H290EC	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290EC	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF- H290T	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290T	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF- HQ190	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ190	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF- HQ290	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ290	Same as above
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP170N	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP170N	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL	Same as above

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VIDEOSCOPE OLYMPUS GIF-XP290N		VIDEOSCOPE OLYMPUS GIF-XP290N	
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XZ1200	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XZ1200	Same as above
EVIS LUCERA ELITE PLEURA VIDEOSCOPE OLYMPUS LTF-H290	Class IIa	EVIS LUCERA ELITE PLEURA VIDEOSCOPE OLYMPUS LTF-H290	Same as above
ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-10	Class IIa	ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-10	Same as above
ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-5	Class IIa	ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-5	Same as above
ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S300-10-3D	Class IIa	ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S300-10-3D	Same as above
AIRWAY MOBILESCOPE OLYMPUS MAF-DM2	Class IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-DM2	Same as above
AIRWAY MOBILESCOPE OLYMPUS MAF-GM2	Class IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-GM2	Same as above
AIRWAY MOBILESCOPE OLYMPUS MAF-TM2	Class IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-TM2	Same as above
Lid MAJ-1024	Class IIa	Lid MAJ-1024	Same as above
Lid MAJ-1025	Class IIa	Lid MAJ-1025	Same as above
Container MAJ-1026	Class IIa	Container MAJ-1026	Same as above
O-ring MAJ-1028	Class IIa	O-ring MAJ-1028	Same as above
CYLINDER HOSE FOR UHI-3 MAJ-1080	Class IIa	CYLINDER HOSE FOR UHI-3 MAJ-1080	Same as above
CYLINDER HOSE FOR UHI-3 MAJ-1081	Class IIa	CYLINDER HOSE FOR UHI-3 MAJ-1081	Same as above
CYLINDER HOSE FOR UHI-3 MAJ-1082	Class IIa	CYLINDER HOSE FOR UHI-3 MAJ-1082	Same as above
MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1084	Class IIa	MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1084	Same as above
MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1085	Class IIa	MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1085	Same as above
AIR/WATER VALVE MAJ-1444	Class IIa	AIR/WATER VALVE MAJ-1444	Same as above
PROBE DRIVING UNIT MAJ-1720	Class IIa	PROBE DRIVING UNIT MAJ-1720	Same as above
RESERVOIR TANK MAJ-1727	Class IIa	RESERVOIR TANK MAJ-1727	Same as above
GAS TUBE MAJ-1741	Class IIa	GAS TUBE MAJ-1741	Same as above
LOW FLOW GAS TUBE MAJ-1742	Class IIa	LOW FLOW GAS TUBE MAJ-1742	Same as above

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EXTRA LOW FLOW GAS TUBE MAJ-1816	Class IIa	EXTRA LOW FLOW GAS TUBE MAJ-1816	Same as above
HAND COIL MAJ-1859	Class IIa	HAND COIL MAJ-1859	Same as above
REFERENCE PLATE MAJ- 1860	Class IIa	REFERENCE PLATE MAJ-1860	Same as above
ENDOSCOPE POSITION MARKING PROBE MAJ-1878	Class IIa	ENDOSCOPE POSITION MARKING PROBE MAJ- 1878	Same as above
CYLINDER HOSE WITH SWITCH-OVER VALVE (PIN- INDEX) MAJ-1985	Class IIa	CYLINDER HOSE WITH SWITCH-OVER VALVE (PIN-INDEX) MAJ-1985	Same as above
CYLINDER HOSE WITH SWITCH-OVER VALVE (DIN) MAJ-1986	Class IIa	CYLINDER HOSE WITH SWITCH-OVER VALVE (DIN) MAJ-1986	Same as above
GAS/WATER VALVE MAJ- 2010	Class IIa	GAS/WATER VALVE MAJ- 2010	Same as above
AUXILIARY WATER TUBE MAJ-2021	Class IIa	AUXILIARY WATER TUBE MAJ-2021	Same as above
INSUFFLATION TUBE MAJ- 590	Class IIa	INSUFFLATION TUBE MAJ-590	Same as above
AUXILIARY WATER TUBE MAJ-855	Class IIa	AUXILIARY WATER TUBE MAJ-855	Same as above
WATER CONTAINER MAJ-902	Class IIa	WATER CONTAINER MAJ-902	Same as above
Probe/Irrigation Plug MD-807	Class IIa	Probe/Irrigation Plug MD- 807	Same as above
AIR/WATER VALVE MH-438	Class IIa	AIR/WATER VALVE MH- 438	Same as above
BALLOON CONTROL UNIT OBCU OBCU	Class IIa	BALLOON CONTROL UNIT OBCU OBCU	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS PCF-H190DI	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS PCF-H190DI	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS PCF-H190DL	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS PCF-H190DL	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS PCF-H190TI	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS PCF-H190TI	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS PCF-H190TL	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS PCF-H190TL	Same as above
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290DL	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290DL	Same as above
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290TI	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290TI	Same as above
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290TL	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290TL	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290ZI	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290ZI	Same as above
EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290ZL	Class IIa	EVIS LUCERA ELITE COLONOVideoscope OLYMPUS PCF-H290ZL	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS PCF-HQ190I	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS PCF-HQ190I	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS PCF-HQ190L	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS PCF-HQ190L	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS PCF-PH190I	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS PCF-PH190I	Same as above
EVIS EXERA III COLONOVideoscope OLYMPUS PCF-PH190L	Class IIa	EVIS EXERA III COLONOVideoscope OLYMPUS PCF-PH190L	Same as above
POWERSPIRAL CONTROL UNIT PCSU	Class IIa	POWERSPIRAL CONTROL UNIT PCSU	Same as above
INTESTINAL Videoscope OLYMPUS PSF-1	Class IIa	INTESTINAL Videoscope OLYMPUS PSF-1	Same as above
EVIS EXERA III SMALL INTESTINAL Videoscope OLYMPUS SIF-H190	Class IIa	EVIS EXERA III SMALL INTESTINAL Videoscope OLYMPUS SIF-H190	Same as above
EVIS LUCERA ELITE SMALL INTESTINAL Videoscope OLYMPUS SIF-H290S	Class IIa	EVIS LUCERA ELITE SMALL INTESTINAL Videoscope OLYMPUS SIF-H290S	Same as above
SINGLE USE SPLINTING TUBE ST-CB1	Class IIa	SINGLE USE SPLINTING TUBE ST-CB1	Same as above
SINGLE USE SPLINTING TUBE ST-SB1	Class IIa	SINGLE USE SPLINTING TUBE ST-SB1	Same as above
EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS TGF-UC180J	Class IIa	EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS TGF-UC180J	Same as above
DUODENOVideoscope OLYMPUS TJF-Q170V	Class IIa	DUODENOVideoscope OLYMPUS TJF-Q170V	Same as above
EVIS EXERA III DUODENOVideoscope OLYMPUS TJF-Q190V	Class IIa	EVIS EXERA III DUODENOVideoscope OLYMPUS TJF-Q190V	Same as above
EVIS LUCERA ELITE DUODENOVideoscope OLYMPUS TJF-Q290V	Class IIa	EVIS LUCERA ELITE DUODENOVideoscope OLYMPUS TJF-Q290V	Same as above
ENDOSCOPIC CO2 REGULATION UNIT OLYMPUS UCR	Class IIa	ENDOSCOPIC CO2 REGULATION UNIT OLYMPUS UCR	Same as above
ULTRASONIC PROBE UM-3R	Class IIa	ULTRASONIC PROBE UM-3R	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre- application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ULTRASONIC PROBE UM-S20-17S	Class IIa	ULTRASONIC PROBE UM-S20-17S	Same as above
ULTRASONIC PROBE UM-S20-20R	Class IIa	ULTRASONIC PROBE UM-S20-20R	Same as above
ENDOSCOPE POSITION DETECTING UNIT UPD-3	Class IIa	ENDOSCOPE POSITION DETECTING UNIT UPD-3	Same as above
URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3	Class IIa	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3	Same as above
URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3R	Class IIa	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3R	Same as above
HIGH FLOW INSUFFLATION UNIT UHI-4	Class IIa	HIGH FLOW INSUFFLATION UNIT UHI-4	Same as above
SINGLE USE SUCTION VALVE (Sterile) MAJ-209	Class Is	SINGLE USE SUCTION VALVE (Sterile) MAJ-209	Certificate # DD 60144068 0001 NB # 0197
SINGLE USE BIOPSY VALVE MAJ-210	Class Is	SINGLE USE BIOPSY VALVE MAJ-210	Certificate # DD 60144068 0001 NB # 0197
SINGLE USE BIOPSY VALVE MAJ-1555	Class Is	SINGLE USE BIOPSY VALVE MAJ-1555	Certificate # DD 60144068 0001 NB # 0197
SINGLE USE DISTAL COVER MAJ-2315	Class Is	SINGLE USE DISTAL COVER MAJ-2315	Certificate # DD 60144068 0001 NB # 0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/23	OMSC_CL607_CL_2024-01-23	Initial issue
2024/04/25	OMSC_CL607_CL_2024-04-25	Revise the letter to be align with OMSC_PLA0_HZ_20240416_EU 2023_607. <ul style="list-style-type: none"> to remove EVIS EUS ENDOSCOPIC ULTRASOUND CENTER EU-ME3, HIGH FLOW INSUFFLATION UNIT UHI-5, HEATABLE INSUFFLATION TUBE MAJ-2464, TUBING SET FOR TRANSANAL SURGERY MAJ-2465 and Table 2. to add HIGH FLOW INSUFFLATION UNIT UHI-4. Update device name from Single Use Biopsy Forceps FB-456D to ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120108) and ULTRASONIC

Date	NB internal reference traceable to each version of the letter	Action
		<p>BIPOLAR GENERATOR USG-410 (EMDN: Z120109).</p> <ul style="list-style-type: none">- Update legacy device name from Single Use Biopsy Forceps FB-215U, FB-216U to Single Use Biopsy Forceps FB-215U.
2024/04/30	OMSC_CL607_CL_2024-04-30	<p>Correction made on Table 1 in the previous version.</p> <ul style="list-style-type: none">- ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120109)- URETERO-RENO FIBERSCOPE URF-P7- URETERO-RENO FIBERSCOPE URF-P7R