

# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 2158445-1

Organization: OLYMPUS MEDICAL SYSTEMS CORP.  
2951 Ishikawa-cho  
Hachioji-shi, Tokyo  
192-8507 Japan

Scope: Design and Development, Manufacture, Distribution, Service, Quality Assurance, Regulatory Affairs, Planning, Delivery support of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units, Ultrasound Surgical Equipment, Ultrasonic surgical system generator, Ultrasonic surgical system transducer, Hard-tissue ultrasonic surgical system holder/tip, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150242490-301

Effective date: 2022-03-07

Expiry date: 2024-07-26

Issue date: 2022-03-07



*Ning Chang*

Ning N. C. Chang

TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



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2951 Ishikawa-cho  
Hachioji-shi, Tokyo  
192-8507 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o OLYMPUS MEDICAL SYSTEMS CORP. Ishikawa Office 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan	Design and Development, Service, Administration, Management, Quality Assurance, Regulatory Affairs, Planning, Delivery support
/02	c/o OLYMPUS MEDICAL SYSTEMS CORP. Shinjuku Monolith Office Shinjuku Monolith, 3-1 Nishishinjuku 2-chome, Shinjuku-ku, Tokyo 163-0914 Japan	Quality Assurance for domestic market
/03	c/o OLYMPUS MEDICAL SYSTEMS CORP. Shirakawa Facility 3-1 Okamiyama, Odakura, Nishigo- mura, Nishishirakawa-gun, Fukushima 961-8061 Japan	Service and Quality Assurance

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192-8507 Japan

The scope of certification also covers the following:

/04 c/o OLYMPUS MEDICAL SYSTEMS Quality Assurance  
CORP.  
Aizu Facility  
3-1-1 Niiderakita,  
Aizuwakamatsu-shi, Fukushima  
965-8520 Japan

TÜVRheinland®

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192-8507 Japan

The scope of certification also covers the following:

/05	c/o OLYMPUS MEDICAL SYSTEMS CORP. Aomori Facility 2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357 Japan	Quality Assurance of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation /Control Units, Camera Heads/Pumps/Monitors /Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units and Ultrasound Surgical Equipment, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump
		Design and Development of Endotherapy Devices, Sterile Endotherapy Devices used in conjunction with Endoscopes

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