

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1627783-1

Organization: Olympus Europa SE & Co. KG
Wendenstr. 20
20097 Hamburg
Germany

Scope: Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy

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.: 3345381-150
Effective date: 2021-12-01
Expiry date: 2023-06-20
Issue date: 2021-12-01



D. Wiedemuth
Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Olympus Europa SE & Co. KG Wendenstr. 20 20097 Hamburg Germany	Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy
/02	c/o Olympus Europa SE & Co. KG Albert-Schweitzer-Ring 24-26 22045 Hamburg Germany	Servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories in the field of endoscopy
/03	c/o Olympus Deutschland GmbH Albert-Schweitzer-Ring 35 22045 Hamburg Germany	Servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories in the field of endoscopy
/04	c/o Olympus Deutschland GmbH Wendenstr. 20 20097 Hamburg Germany	Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy

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Germany

The scope of certification also covers the following:

- | | | |
|-----|-------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /06 | c/o Olympus France S.A.S.
65 Rue de Monthléry
94150 Rungis
France | Servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories in the field of endoscopy |
| /08 | c/o OLYMPUS IBERIA S.A.U.
PL. Europa 29-31
08908 L'Hospitalet de Llobregat,
Barcelona
Spain | Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy |
| /11 | c/o Olympus France S.A.S.
19 rue d'Arcueil
94150 Rungis
France | Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy |
| /13 | c/o Olympus Czech Group, s.r.o.
člen koncernu
Evropská ul. 176/16
160 41 Praha 6
Czech Republic | Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy |

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- | | | |
|-----|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /14 | c/o Olympus Czech Group, s. r.o.
člen koncernu
Telickova 457/29
751 24 Prerov-Predmosti
Czech Republic | Servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories in the field of endoscopy |
| /19 | c/o Olympus Medical Products Portugal
UNIPESOAL, LDA
Rua de Alcorredores 43 A
3020-923 Torre de Vilela (Coimbra)
Portugal | In-house servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories in the field of endoscopy |
| /20 | c/o Olympus Austria GmbH
Shuttleworthstr. 25
1210 Wien
Austria | Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy |
| /21 | c/o Olympus Nederland B.V.
Simon Smitweg 18
2353 GA Leiderdorp
Netherlands | Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy |

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|-----|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /23 | c/o Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Switzerland | Servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories in the field of endoscopy |
| /24 | c/o Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Switzerland | Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy |

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