

# CERTIFICATE

No. Q5 17 07 34400 015



Product Service

Holder of Certificate: **OPTOMIC ESPAÑA, S.A.**Madroño 4 F- P. Ind. La Mina  
28770 Colmenar Viejo, Madrid  
SPAIN

Facility(ies):

OPTOMIC ESPAÑA, S.A.  
Madroño 4 F- P. Ind. La Mina, 28770 Colmenar  
Viejo, Madrid, SPAIN

Certification Mark:



**Scope of Certificate:** Design and Development, Production, Distribution, Sale, Installation and Technical Service of Microscopes, Colposcopes, Rigid and Flexible Endoscopes, Cold Light Sources, Camera Systems, Optic Systems, Diagnostic Workstations, Cameras for Endoscopy, Examination Chairs, Stroboscopes and Sale of Medical Equipment

**Applied Standard(s):**

EN ISO 13485:2016  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713103049

Valid from: 2017-07-31

Valid until: 2020-07-28

Date, 2017-07-31

Stefan Preiß

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DAKKS

Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



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## Declaration of Conformity *Declaración de Conformidad*

OPTOMIC ESPAÑA, S.A.  
Madroño 4 F - P. Ind. La Mina  
28770 Colmenar Viejo, Madrid  
SPAIN

Declares under its responsibility that the Class IIa product:  
*Declara bajo su responsabilidad que el producto de Clase IIa:*

**FLEXIBLE ENDOSCOPES OP-14 WCH, OP-20, OP-40, OP-50**  
**ENDOSCOPIO FLEXIBLE OP-14 WCH, OP-20, OP-40, OP-50**  
**RIGID ENDOSCOPE: SINUSCOPE, HYSTEROSCOPE/ LAPAROSCOPE**  
**ENDOSCOPIO RIGIDO: SINUSCOPIO/HISTEROSCOPIO/LAPAROSCOPIO**  
**DIAGNOSTIC WORKSTATION OPTIMUS AND OTOSMART**  
**UNIDAD DE TRABAJO OPTIMUS Y OTOSMART**

is in conformity with the legislation of the Directives 93/42/EEC and 2007/47/CE concerning Medical Devices and complies with the standards included in the technical files.  
*es conforme a las disposiciones de las Directivas 93/42/CEE y 2007/47/CE relativas a Productos Sanitarios y cumple con las normas incluidas en la documentación técnica.*

Our Quality Management System, with its continuing certification, guarantees that our products meet the required quality demands.  
*Nuestro Sistema de Gestión de Calidad, con su certificación continua, garantiza que nuestros productos cumplen con las exigencias de calidad requeridas.*

This Declaration is supported by EC No. G1 17 07 34400 016, under Annex II.3 of the Directive 93/42/EEC, issued by TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany.  
*Esta Declaración se encuentra respaldada por EC Nº. G1 17 07 34400 016, bajo el Anexo II.3 de la Directiva 93/42/CEE, emitido por TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Alemania.*

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.  
*De acuerdo con la Directiva del Consejo nº 93/42/CEE relativa a los productos sanitarios, la empresa TÜV SÜD Product Service GmbH es el Organismo Notificado con el nº de identificación 0123.*

Date of issue / *Fecha de emisión:* 31/07/2017  
Valid until / *Válido hasta:* 18/02/2019

F.O.  
JRF

Jorge Rial Ferrario  
General Manager  
In/En Colmenar Viejo, Spain



Declaration of Conformity  
*Declaración de Conformidad*

OPTOMIC ESPAÑA, S.A.  
Madroño 4 F - P. Ind. La Mina  
28770 Colmenar Viejo, Madrid  
SPAIN

Declares under its responsibility that the Class I product:  
*Declara bajo su responsabilidad que el producto de Clase I:*

**COLPOSCOPE OP-C2, OP-C2L and OP-C5 and ACCESSORIES**  
*COLPOSCOPIOS OP-C2, OP-C2L Y OP-C5 Y ACCESORIOS*  
**MICROSCOPES OP-C12 and OP-C16 and ACCESSORIES**  
*MICROSCOPIO OP-C12 Y OP-C16 Y ACCESORIOS*  
**BEAM SPLITTERS OP-TV CLICK, OP-TV, OP-TV.DC, OP-TV6, OP-TV8 and OP-TV10HD**  
*DIVISOR DE IMAGEN OP-TV CLICK, OP-TV, OP-TV.DC, OP-TV6, OP-TV8 y OP-TV10HD*  
**LIGHT SOURCES FIBROLUX 150, LED HP, and OP-LS5**  
*FUENTE DE LUZ FIBROLUX 150, LED HP, y OP-LS5*  
**LED HEAD LAMPS OP-HL7, OPHL15 and OP-LF5**  
*FOTÓFORO OP-HL7, OP-HL15 Y OP-LF5*  
**STROBOSCOPES STROBOLUX III LED and STROBOLUX III LED + HD**  
*ESTROBOSCOPIO STROBOLUX III LED and STROBOLUX III LED + HD*  
**CCD CAMERA OP-714 and OP-1428**  
*CÁMARAS OP-714 y OP-1428*  
**TROLLEYS STANDARD, COMPACT and PROFESSIONAL**  
*MUEBLES DE ENDOSCOPIA STANDARD, COMPACT y PROFESSIONAL*  
**ENT CHAIRS OP-S4, OP-S6, OP-S7, OP-S8, OP-S10, OP-S14 and ACCESSORIES**  
*SILLONES ORL OP-S4, OP-S6, OP-S7, OP-S8, OP-S10 y OP-S14 y ACCESORIOS*  
**CHAIR OP-G7 and ACCESSORIES**  
*SILLÓN OP-G7 Y ACCESORIOS*  
**RIGID ENDOSCOPES: OTOSCOPE/LARYNGOSCOPE**  
*ENDOSCOPIOS RIGIDOS: OTOSCOPIO/ LARINGOSCOPIO*  
**FIBERSCOPES OP-30**  
*FIBROSCOPIO OP-30*

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Date of issue: 31/07/2017

*Fecha de emisión:*

Valid until: 28/07/2020

*Válido hasta:*

P.O.  
JRF

Jorge Rial Ferrario  
General Manager  
In/En Colmenar Viejo, Spain