



# EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 005354 0002 Rev. 01**

**Manufacturer:** **Ningbo Wise OptoMech Technology Corporation**

No.86, Building 11, Innovation Park 128, Qiming Road  
Yinzhou District  
315100 Ningbo  
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies): Digital Endoscope System,  
Single-Use Digital Flexible Endoscope**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10053540002Rev.01](http://www.tuvsud.com/ps-cert?q=cert:G10053540002Rev.01)

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**Date,** 2021-04-22

Christoph Dicks  
Head of Certification/Notified Body