

## EC Declaration of conformity

Product name :	Ophthalmoscope
Brand name :	nun
Model name :	WFE-02S
Manufacturer :	WIKIOPTICS, Inc.
Manufacturer Address :	Room 205, U-tower, 120, Heungdeokjungang-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 16950, Republic of Korea
EU Representative :	JaviTech e. K.
EU Representative Address :	Sachsenhausener StraBe 16, 65824 Schwalbach am Taunus, Germany

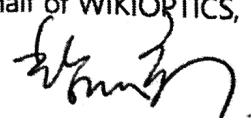
We declare that the medical device described hereafter;  
Ophthalmoscope / WFE-02S has been classified as Class I (Annex IX Rule 12) and is in conformity  
with the essential requirements and provisions of Council Directive MDD 93/42/EEC  
(Medical Device Directive).

### Standards applied :

Reference number	Title
IEC60601-1 : 2012 (Edition 3.1)	Medical electrical equipment – Part 1 : General requirements for basic safety and essential performance
EN60601-1-2 : 2007	Medical electrical equipment – Part1-2 : General requirements for basic safety and essential performance – Collateral standard : electromagnetic compatibility – Requirements and tests
EN62304	Medical device software – Software Life-Cycle Processes
EN62366	Medical devices – Application of usability engineering to medical devices
IEC62133 : 2012 (2 <sup>nd</sup> edition)	Safety test standard of Li-ion battery

22. Nov. 2017

Yim, BooBin / CEO  
On behalf of WIKIOPTICS, Inc.



# G-CERTI Certificate

*G-CERTI hereby certifies that*

**WIKIOPTICS Co., Ltd.**

**Rm. 205, 120, Heungdeokjungang-ro, Giheung-gu, Yongin-si,  
Gyeonggi-do, Korea**

*Has been audited by G-CERTI and has implemented*

*Medical Devices-Quality Management Systems*

## ISO 13485:2016

*Scope of Registration*

**Manufacturing, Purchase, Sales of Medical Device  
(Ophthalmoscope)**

**Issue Date : 11 Oct. 2017**  
**Expiry Date : 10 Oct. 2020**  
**Original Date : 11 Oct. 2017**  
**Certification No : GIS - 0968 - MD**

  
Chief Executive



To verify the validity of this certificate please visit [www.gcrti.com](http://www.gcrti.com)

This is to certify that the Management Systems of this company has been found to conform to the above G-CERTI FI-12-03

