

# DECLARATION OF CONFORMITY

Certificate #GSC072207

This certificate is effective 05 March 2021 and valid for the devices described below and bearing the CE Mark and originating from GSC in Ann Arbor, MI USA.

Product Registration Mark (CE)



Application of Council Directive  
(EC Directives)

Quality System Registration Mark



Standard(s) to which product is declared:

Self Declaration (Class 1)  
MDR-EU 2017/745 rule III, 4.1

Manufacturer:

General Scientific Corporation  
77 Enterprise Drive  
Ann Arbor, Michigan 48103 USA

Models:

GL215N, GL215F, GL275N, GL275F, GL275XF,  
GL300N, GL300M, GL300F, GL300XF  
iM275N, iM275F, iM275XF  
EVW200N, EVW200F, EVW300N, EVW300M, EVW300F  
EVX250N FLM, EVX250F FLM, EVX250XF FLM  
EV200N FLM, EV200F FLM, EV250N FLM, EV250M FLM, EV250F FLM, EV250XF FLM  
EV300N FLM, EV300M FLM, EV300F FLM, EV300XF FLM  
EVC250N FLM, EVC250M FLM, EVC250F FLM, EVC250XF FLM  
EVC300N FLM, EVC300M FLM, EVC300F FLM, EVC300XF FLM  
EVK300 FLM, EVK350 FLM, EVK450 FLM, EVK550 FLM, EVK650 FLM, EVK800 FLM,  
EVK1000 FLM, MICRO250N FLM, MICRO250F FLM, MICRO250XF FLM  
MICRO300N FLM, MICRO300M FLM, MICRO300F FLM,  
EV250 TTL, EVX250 TTL, EVC250 TTL, EVC300 TTL,  
EVK300 TTL, EVK350 TTL, EVK450 TTL, EVK550 TTL, EVK650 TTL, EVK800 TTL  
MICRO250 TTL, MICRO300 TTL, MICRO EVK300 FLM, MICRO EVK350 TTL  
MICRO EVK400 FLM, MICRO EVK400 TTL  
EViM250N, EViM250M, EViM250F, EViM250XF  
EVCiM250N, EVCiM250M, EVCiM250F, EVCiM250XF  
EVCiM300N, EVCiM300M, EVCiM300F, EVCiM300XF  
EVKiM300, EVKiM350, EVKiM400, EVKiM450, EVKiM500, EVKiM550  
EVKiM650, EVKiM800, EVKiM1000, iMK400, iMK500  
KL400, KL500  
MV250N, MV250F, SL2.0N, SL2.0F, SL2.5N, SL2.5F, ST250

Description:

SurgiTel Custom Magnification Loupes

Type of Equipment:

Visual Magnification

"I, the undersigned, hereby declare that the equipment specified herein conforms to the applicable provisions of the above directives and international standards

Signature:

Date:

04/23/2021

Name:

B. J. Chang, President

Authorized European

Representative, EC/REP: CTM GmbH

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Sedelfeldberg 10 a, D-86316 Friedberg

Germany

Signature:

Date:

03/24/2021

Name:

Heinrich Tüttemann, Managing Director