

Ce document complémentaire GMED n° 37371 rev. 2 atteste de la validité du certificat CE n° 33865 rev. 5 au regard des informations listées ci-dessous.

This GMED additional document N° 37371 rev. 2 attests to the validity of CE certificate n° 33865 rev. 5 with regard to the information listed below.

Fabricant / Manufacturer:

Optalmed, LLC.

**1249 Quarry Lane, Suite 140,
PLEASANTON, CA 94566 UNITED STATES**

Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessoires marqués CE <i>Device designation / EC marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD Class</i>
Disposable Iris Retractors, 1 set of 5 retractors	7001	IIa
Disposable Iris Retractors, 6 sets of 5 retractors	7002	
Reusable Iris Retractors, 1 set of 6 retractors	7003	
Disposable Flat Iris Retractors, 1 set of 5 retractors	7004	
Multiport Focal Light Fiber, O PK, 20Ga, 5 assys	7005	
Multiport Wide View Light Fiber, O PK, 20Ga, 5 assys	7006	
Multiport Shielded Light Fiber, O PK, 20Ga, 5 assys	7007	
Multiport Focal Ultra Bright Light Fiber, O PK, 23Ga, 5 assys	7008	
Multiport Wide View Ultra Bright Light Fiber, O PK, 23Ga, 5 assys	7009	
Multiport Shielded Ultra Bright Light Fiber, O PK, 23Ga, 5 assys	7010	
Multiport Focal Ultra Bright Light Fiber, O PK, 25Ga, 5 assys	7011	
Multiport Chandelier Ultra Bright with Adjustable Stopper, O PK, 25Ga, 5 assys	7012	
Disposable Flat Iris Retractor, 6 sets of 5 retractors	7013	

GMED 0459

GMED - 37371 rev. 2
Modifie le document n° 37371 rev. 1



DocuSigned by:

Beatrice Lys
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**On behalf of the President
Béatrice LYS
Technical Director**

Sites couverts et Activités / Locations and Activities

Sites / Locations	Activités / Activities
Optalmed, LLC 1249 Quarry Lane, Suite 140 Pleasanton, CA 94566 - USA	Conception, fabrication et contrôle final <i>Design, manufacturing and final control</i>

Modifications / Modifications

Identification des modifications apportées au certificat CE n° 33865 rev. 5:

Identification of the modifications made to the CE certificate n° 33865 rev. 5:

Modifications / Modifications	Dossier(s) / File(s) N°	Date / Date
Nouvelle référence de rapport dans le cadre du maintien de la certification / New file reference in the framework of the maintenance of the certification	T001083-P3-S1 & T001083-P4-S2	17 août 2021 <i>August 17th, 2021</i>



GMED - 37371 rev. 2
 Modifie le document n° 37371 rev. 1



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Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director