

EU-DECLARATION OF CONFORMITY

1. Manufacturer OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

Single Registration-No. JP-MF-000008016

2. Article(REF)No. / Article Name Please refer to Attachment 1

3. Product designation Please refer to Attachment 1

4. Serial or Lot No. range Please refer to Attachment 1

5. Product classification Please refer to Attachment 1

6. Authorized representatives in EU

Name Olympus Europa SE & Co. KG

Address Wendenstrasse 20, 20097 Hamburg, Germany

Single Registration-No. DE-AR-000006774

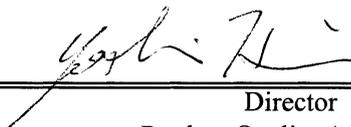
7. Declaration

This declaration was made in sole responsibility of the manufacturer.
The stated product complies with the requirements of following European Directives and Regulations.

The declarations is based on: (EU)2017/745 Annex II,III
2011/65/EU, (EU) 2015/863

Place, Date: Tokyo, 2022/8/29

Signature:



Director
Product Quality Assurance
Medical Quality Assurance and Regulatory Affairs
Yoshihito Horikawa

ATTACHMENT 1



◆The EU-Declaration of Conformity is valid for the following articles:

Product designation	Article(REF)No. / Article Name	Serial or Lot No. range	Remark	UDI-DI
VISERA ELITE III LED LIGHT SOURCE CLL-S700	OLYMPUS CLL-S700	From 7200158 to	-	04953170433436

GMDN	EMDN	Basic UDI-DI	Classification*	Rule*
35158	Z120204	495317000099C4	Class I	10

* According to Annex VIII for (EU) 2017/745, Annex IX for 93/42 /EEC

◆Applied Standards [RoHS,RED,LVD,EMC]

[RoHS]	EN IEC 63000 : 2018
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Refer to the GSPR Checklist for above mentioned product. [MDR]

◆Intended purpose (MDR only) / Product Description:

This light source is intended to provide light to a endoscope/video endoscope in order to process electronic signals transmitted from them and output image signal to monitor, and to be used with Olympus endoscopes, video endoscopes, camera heads, video system center, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

◆ Serial or Lot No.

Directive/Regulation	Re-issued DoC-Serial or Lot No. range Starting from	Ended at	New DoC-Serial or Lot No. range Starting from
(EU)2017/745	-	-	7200158
2011/65/EU, (EU) 2015/863	-	-	-