

**EU-DECLARATION OF CONFORMITY**

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**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.

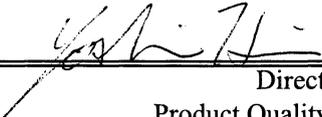
The declarations is based on: (EU)2017/745 Annex II,III  
2011/65/EU, (EU) 2015/863

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**Place, Date:** Tokyo, 2022/8/29

**Signature:**

  
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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 VIDEO SYSTEM CENTER OTV-S700	OLYMPUS OTV-S700	From 7200168 to	-	04953170433337

GMDN	EMDN	Basic UDI-DI	Classification*	Rule*
18034	Z120204	495317000099C4	Class I	13

\* 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 video system center is intended to be used with OLYMPUS camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.
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◆ 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	-	-	7200168
2011/65/EU, (EU) 2015/863	-	-	-