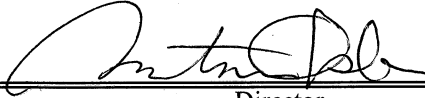


EU-DECLARATION OF CONFORMITY

1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
Single Registration-No.	N/A
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 14-18, 20097 Hamburg, Germany
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:	93/42/EEC 2011/65/EU, (EU) 2015/863
	Annex II
8. Notified Body for MDD	
Issued by	TÜV Rheinland LGA Products GmbH
Address	Tillystraße 2, 90431 Nürnberg, Germany
Registration-No.	Registration-No.0197

Place, Date: Tokyo, 2020/1/15

Signature:



Director
Product Quality Assurance
Medical Quality Assurance and Regulatory Affairs
Mitsumasa Okada

ATTACHMENT 1



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

Product designation	GMDN	Article(REF)No. Article Name	Serial or Lot No. range	UDI-DI	Basic UDI-DI	Classification
THUNDERBEAT Open Fine Jaw TypeX	64246	TB-0009OFX	From 9ZK to	N/A	N/A	Class IIb

◆ Applied Standards [RoHS,RED,LVD,EMC]

[RoHS] EN50581:2012

Refer to the Essential Requirements Checklist for above mentioned product. [MDD]

◆ Included items

Product designation	Article(REF)No. Article Name
N/A	N/A

◆ Intended purpose:

The THUNDERBEAT Open Fine Jaw Type X hand instrument is intended to be used for open surgery to cut, seal, coagulate, grasp, and dissect. Seal & Cut mode: The THUNDERBEAT Open Fine Jaw Type X hand instrument when used in combination with the Seal & Cut mode is indicated for open, general surgery (including plastic and reconstructive, etc.), or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. The device has been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics. This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, radical neck dissection, and tonsillectomy) for only ligation (sealing and cutting) of vessels, lymphatics, and tissue bundles 2 – 3 mm *1 away from unintended thermally sensitive structures such as nerves and parathyroid glands. Seal mode: The THUNDERBEAT Open Fine Jaw Type X hand instrument when used in combination with the Seal mode is indicated for open, general surgery (including plastic and reconstructive, etc.), or in any procedure in which vessel sealing, coagulation, grasping is performed. The device has been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics. This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, radical neck dissection, and tonsillectomy) for sealing of vessels, lymphatics, and tissue bundles 2 – 3 mm *1 away from unintended thermally sensitive structures such as nerves and parathyroid glands. The THUNDERBEAT Open Fine Jaw Type X hand instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures. *1 It should be extended appropriately depending on the operation situation.