OLYMPUS

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 20, 20097 Hamburg, Germany *
*Until 31 May 2021 Wendenstrasse 14-18, 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: 93/42/EEC Annex II
2011/65/EU, (EU) 2015/863

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, 2021/7/8

Signature:

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

ATTACHMENT 1

OLYMPUS

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

Product designation	GMDN	EMDN (CND)	Article(REF)No. Article Name	Serial or Lot No. range	UDI-DI	Basic UDI-DI	Classification
Ultrasonic Generator	36273	-	USG-400	USG400 : from 9914528 to V2USG400 : from 9115955 to	N/A	N/A	Class IIb

✦Applied Standards [RoHS,RED,LVD,EMC]

[RoHS] EN IEC 63000 : 2018

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 Ultrasonic Generator (USG-400) is intended to be used with the Electrosurgical Generator (ESG-400), the THUNDERBEAT Transducer (TDTB400), the SONICBEAT Transducer (TD-SB400), the THUNDERBEAT, and / or the SONICBEAT for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.

✦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
93/42/EEC	USG400 : 9100031 V2USG400 : 9608649	-	-
2011/65/EU	USG400 : 9303149 V2USG400 : 9608649	USG400 : 9914527 V2USG400 : 9115944	-
2011/65/EU, (EU) 2015/863	-	-	USG400 : 9914528 V2USG400 : 9115955