

CONFIRMATION OF CONFORMITY (MDD)

1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	
	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan	
2. Article(REF)No. / Article Name	TB-0009OFX	
3. Product designation	THUNDERBEAT Open Fine Jaw TypeX	
4. Serial or Lot No. range	From 9ZK to	
5. GMDN	64246	
6. Confirmation/Classification	93/42/EEC	Class IIb
7. Classification with rule/Annex	9-2	Annex II
8. Manufacturing site	Aomori	
9. Sterilization site	Japan Gas Co.,Ltd.	
10. Sterilization method	EOG	
11. Expiration date	3 years	
12. Technical Documents / Records	Refer to the Essential Requirements Checklist for above mentioned product. [MDD]	

Place, Date: Tokyo, 2020/1/15

Signature:



Regulatory Affairs Intelligence,
Regulatory Strategy and Management,
Medical Quality Assurance and Regulatory Affairs
Tomohiko Oda