Declaration of Conformity

Manufacturer Name	Micro-Tech (Nanjing) Co., Ltd.
Address	No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, People's Republic of China
SRN	CN-MF-000006950
EU Authorized Representative Name	Shanghai International Holding Corp. GmbH (Europe)
Address	Eiffestrasse 80, 20537 Hamburg Germany
SRN	DE-AR-000000001
Product name	Disposable Bite Block
Product Trade Name	Disposable Bite Block
Basic UDI-DI	6902284BB341436P
Catalogue Number	Please see Attachment 1
GMDN code	34143
EMDN code	G030804
Classification	Class I (according to Annex VIII of Regulation(EU)2017/745)
Conformity Assessment Route	Annex II, III, IV of MDR 2017/745
Intended Purpose	The device was supposed to be used for patient that had no serious chronic disease, was able to tolerate endoscopic examination and treatment.

The Declaration of Conformity is issued under the sole responsibility of Micro-Tech (Nanjing) Co., Ltd.. The device that is covered by the present declaration is in conformity with the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

General applicable Regulation:

REGULATION (EU) 2017/745 of medical device

Standard Applied:

All other applicable union legislations, harmonized standards and common specification (published in the Official Journal of the European Communities)

✧ EU Regulation 2017/745

✧ EN ISO13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes

✧ ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

✧ EN 1041:2008+A1:2013 Information supplied by the manufacturer with medical devices

✧ EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

✧ EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing

✧ EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

✧ EN ISO 10993-7:2008/AC: 2009 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residual

✧ EN ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

✧ IMDRF MDCE WG/N56 FINAL: 2019 Clinical Evaluation

✧ EC GUIDE TO GOOD MANUFACTURING PRACTICE REVISION TO ANNEX 1-2003

✧ ASTM F1980-2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

✧ EN 62366-1-2015+AMD1-2020 Medical devices – Application of usability engineering to medical devices

✧ MEDDEV 2.7.1 (Rev. 4, 2016) Clinical evaluation: a guide for manufacturers and notified bodies

- ✧ MDCG 2018-1 Guidance on basic UDI-DI and changes to UDI-DI
- ✧ MDCG-2019-1MDCG guiding principles for issuing entities rules on basic UDI-DI
- ✧ MDCG 2020-5 Guidance on Clinical Evaluation
- ✧ MDCG 2020-6 Guidance on Sufficient Clinical Evaluation
- ✧ ISO/TR 20416 Medical devices — Post market surveillance for manufacturers

Signature: Place and date of issue:

Becky Li ..... Nanjing, 2021-11-03 .....

NAME: Becky Li

Person Responsible for Regulatory Compliance

Attachment 1 Catalogue Number

No.	REF	Description
1	AC01-103.A	New type adult Bite Block+ Spandex Strap
2	AC01-103.P	Child Bite Block+ Spandex Strap
3	AC01-107.M	Old type adult Bite Block+ Spandex Strap
4	AC01-108.A	New type adult Bite Block+ Knitting Strap
5	AC01-108.P	Child Bite Block+ Knitting Strap
6	AC01-102.A	New type adult Bite Block
7	AC01-102.M	Old type adult Bite Block
8	AC01-103.M	Old type adult Bite Block+ Knitting Strap

Revision History

Version	Date	Description
A/0	2021-06-01	Initial
A/1	2021-06-21	Update SRN of Micro-Tech
A/2	2021-09-26	Update SRN of EU Authorized Representative Name and EMDN code