Declaration of Conformity

We, Zumax Medical Co., Ltd.

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Website: www.zumaxmedical.com

Declare on our sole responsibility, that the medical devices:

Name: Binocular Loupes
Model: SLE, SLF, SLH, SLT, SLS, SLD, SLK, DFT, DFK

Basic UDI-DI: 69450955binocularloupesYV

meets all applicable requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) .

Applied standards :	ISO 13485:2016 ISO 14971:2019 ISO 15223-1:2021 IEC 62366-1:2015/Amd1:2020
Classification:	Classified as class I according to Annex VIII, rule1 of the Regulation (EU) 2017/745.
Conformity assessment route:	Conformity assessment was performed according to Annex II and Annex III of the Regulation (EU) 2017/745.
Manufacturer SRN:	CN-MF-000011126
The Authorized Representative within the EU who has been empowered to enter into commitments on our behalf is:	MedNet EC-REP GmbH Borkstrasse 10 48163 Münster, Germany
Authorised Representative SRN:	DE-AR-000000002
Intended Use:	Loupes are designed only for optical magnification during examinations and operations.

The declaration of conformity is valid until a revised declaration of conformity issued.

Date of issue: 11 /(Day) June /(Month) of 2024.

Place of issue: Suzhou , China

Signature (of authorized person): _____

Typed name (of authorized person): JILONG WANG

Position/Title: CEO