Declaration of Conformity

We, Zumax Medical Co., Ltd.

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Tel：+86-512-66650502 Fax: +86-512-66909655
Website: www.zumaxmedical.com

Declare on our sole responsibility, that the medical devices:

Name: Headlight
Model: HL8000, HL8200, HL8260, HL8300, HL8350

Basic UDI-DI: 69450955headlight7K

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 :

	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. (2007) and/or EN 60601-1:2006+A11:2011 EN 60601-1-2:2015 ISO 13485:2016 ISO 14971:2019 ISO 15223-1:2021 IEC 62366-1:2015
Classification:	Classified as class I according to Annex VIII, rule10 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

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

Date of issue: 25 /(Day) May /(Month) of 2023.

Place of issue: Suzhou , China

Signature (of authorized person): _____

Typed name (of authorized person): JILONG WANG

Position/Title: CEO