EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Shenzhen Iboolo Optics Co., Ltd B1-406 Mingyou Purchasing Center, Xixiang St., Bao'an District, Shenzhen, Guangdong, 518102 China
SRN:	CN-MF-000029373
European Representative:	Kingsmead Service B.V. Zonnehof 36, 2632 BE, Nootdorp, Netherland office@kingsmead-service.com SRN:NL-AR-000002066
Product name:	Dermatoscope
Intended Purpose:	The device is an internally powered medical microscope for skin lesions diagnosis. It can be used for both contact and non-contact skin examination with its particularly lighting system. The accessory phone adapter helps connect dermatoscope with smartphone to capture and display images.
Product code / Catalogue number:	DE-200 DE-300 DE-400 DE-3100 DE-4100 DE-5100 DE-6100
Basic UDI-DI:	69232990DE-31005C, 692329904100GM 69232990400UU, 69232990300UP, 69232990200UJ 692329905100GU, 692329906100H3
Classification acc. to MDR Ax. VIII:	Class I, Rule 1
Product Options/Accessories:	*NA*
Conformity assessment procedure:	Annex II + Annex III of MDR

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Signature: Shenzhen Iboolo Optics Co., Ltd

Name: Lily Wang

Title: Director

City: Shenzhen

Date: 21/8/2022

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