

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

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

Lily Wang

Title: Director

City: Shenzhen

Date: 21/8/2022

