

IBOOLO DERMATOSCOPE

DE-4100 • DE-3100 • DE-400 • DE-300 • DE-200 • DE-215



Our Mission

To offer innovative & affordable dermascopes

we want to leverage our expertise in optical fields,
to create medical lenses that benefit humanity.

About Us

We are founded in 2012, is one of the world's leading supplier of smartphone lens. We started and focused on making high-end phone lens for many years ...
But now we do more than that, we want to use our extensive experience and knowledge to make some high quality and affordable dermascope to meet the needs of more people and arouse people's attention to skin problems.

Our Factory

Our factory is equipped with ultra wave cleaning machines, dust-free workshops, and automatic assembly machines to produce optical products with high accuracy and durability.



Certificate

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-00002066

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
Title: Director
City: Shenzhen
Date: 21/8/2022

CE

CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 18514 2509 BC Den Haag

Kingsmead Service B.V.
T.a.v. de heer Jeff
Zonnehof 36
2632 BE Nootdorp

Farmatec
Bezoekadres:
Hofhorren
Kijperslaan 50
2515 XP Den Haag
T 070 340 6161
<http://helpdeskdenfarmatec.nl>

Taalklachten via:
medische_hulpverleners@minvws.nl

Ons kenmerk:
CIBG-20232158

Bijlagen
Uw aanvraag
6 juni 2023

Datum: 7 juli 2023
Betreft: notificatie medisch hulpmiddel klasse I

Geachte heer Jeff,

Hierbij bevestig ik de ontvangst op 6 juni 2023 van de notificatie van het medische hulpmiddel klasse I, dat bedrijf Shenzhen Iboolo Optics Co., Ltd., met Europees gemachtigde Kingsmead Service B.V., als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over dit product het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Dermatoscope
(geen merknaam) (NL-CA002-2023-76116)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken¹ en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd². Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw product overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaand hulpmiddel te registreren in Eudamed.³

¹ O.g.v. art. 29 MDR.
² O.g.v. art. 31 MDR.
³ www.eudamed.europa.eu/help-content/uploads/2018/05/FAQ_MDR_180117_V1.0-Loof. Zie vraag en antwoord nummer 20.

Pagina 1 van 2

Letter of Designation
for EU Representative

Kingsmead Service B.V.
Confirmed that Kingsmead Service B.V. is the European Authorized Representative of

Shenzhen Iboolo Optics Co., Ltd.
B1 406 Mingyou Purchasing Center Building, Xixiang St., Bao'an District, Shenzhen 518102, Guangdong China

And the product(s) below have been registered with Farmatec of Netherlands.

Product name	Registration number
Dermatoscope	NL-CA002-2023-766116

This appointment remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed.
The product liability rests with the manufacturer in accordance with applicable Directive(s)/Regulation(s) and standard(s). Where the manufacturer affixes the CE marking to the product listed, they must ensure that all the requirements of the appropriate EU Directive(s)/Regulation(s) and standard(s) have and continue to be met.
Please inform us of any changes to:

- the company information
- additional generic groups of devices or additional devices
- discontinuation of a generic group of devices or devices

For and on behalf of
Kingsmead Service B.V.
Zonnehof 36, 2632 BE, Nootdorp, Netherland
Lily Wang
Authorized Signature
Only used for the EU Representative Signature

Our Reference: ERU22244
Issued date: July 14, 2023
Page 1 of 1

EC REP Kingsmead Service B.V.
Zonnehof 36, 2632 BE, Nootdorp, Netherland

EUDAMED

CURRENT ACTOR: Manufacturer, CN-MF-000029373, Shenzhen Iboolo Optics Co., Ltd. [China] [Notifications](#)

UDI-DI 06923299016887

[Go back to the list](#)

Manufacturer information

Organisation name: Shenzhen Iboolo Optics Co., Ltd.
Actor ID/SRN: CN-MF-000029373
Address: No. 168 Baoyuan Road Shenzhen, Guangdong
Telephone number: -
Email: iboolo@iboolo.com

Authorised Representative

Organisation name: Kingsmead Service B.V.
Eudamed Actor ID: NL-AR-00002066
Address: 36 Zonnehof Nootdorp
Telephone number: +31(0) 64 6571 005
Email: office@kingsmead-service.com

Basic UDI-DI details

Basic UDI-DI identification

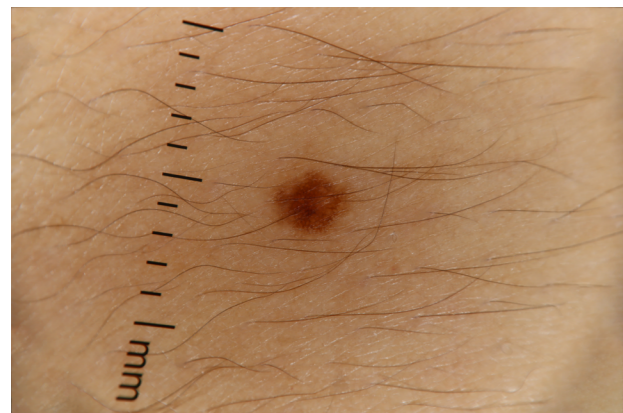
Applicable regulation: MDR (REGULATION) (EU) 2017/745 on medical devices

Basic UDI-DI code: 69232990DE-31005C
Issuing Entity: GS1

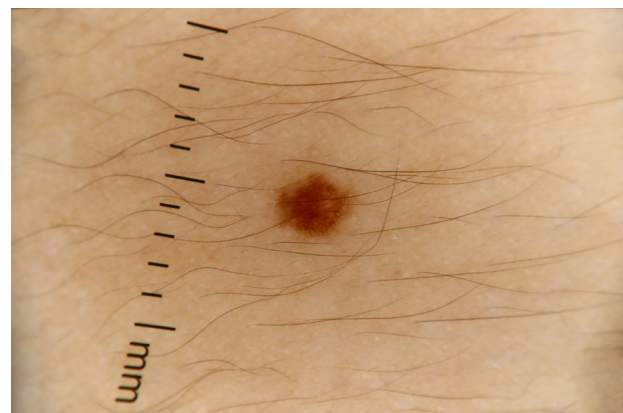
Is it a System or Procedure Pack which is a Device in itself?
No
Special device type: No

Risk class: Class I
Implantable: No
Measuring function: No
Reusable surgical instruments: No
Active device: Yes
Device intended to administer: No

DERMATOSCOPE DE-4100



Non Polarization



Polarization



Features

- 10 x Magnification
- 32mm wide field of view
- Polarized, non-polarized, and amber light illumination
- Detachable protective glass
- Automatic shutdown
- Included adapter fits all phone
- Naked eye detection
- Bright LED illumination lights with 3 levels of brightness control
- All-metal housing

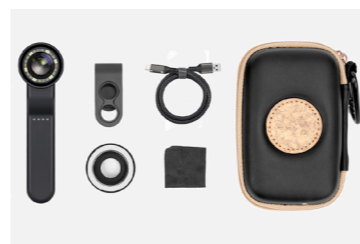
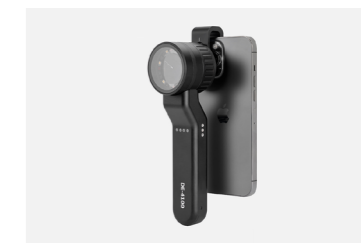
Technical Information

Material	Aluminum & Glass
Optical Design	All glass, 4 elements 3 groups, anti-reflection coating
Lens Diameter	33mm(front); 33mm(rear)
Magnification	10X
Distortion	8%
Polarization	6 LEDs white non polarized, 4 LEDs amber polarized, 12 LEDs white polarized
Resolution	300 LP/MM (Axis) 250 LP/MM (Edge)
LED Type	SMD LED beads
Battery Capacity	1000mAh Lithium ion
Charging	USB-C
Working Time	3-6 hours

Accessories DE-4100



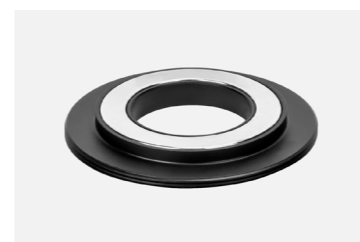
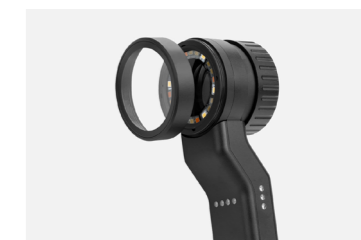
UNIVERSAL PHONE ADAPTER
Save images of lesions on your smartphone



IN THE BOX
Relative accessories included in the package



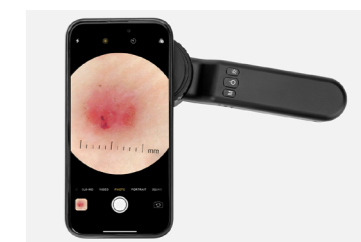
SMALL CONTACT PLATE
To detect difficulty access pigmented lesions



CAMERA ADAPTER
Save images of lesions on your camera



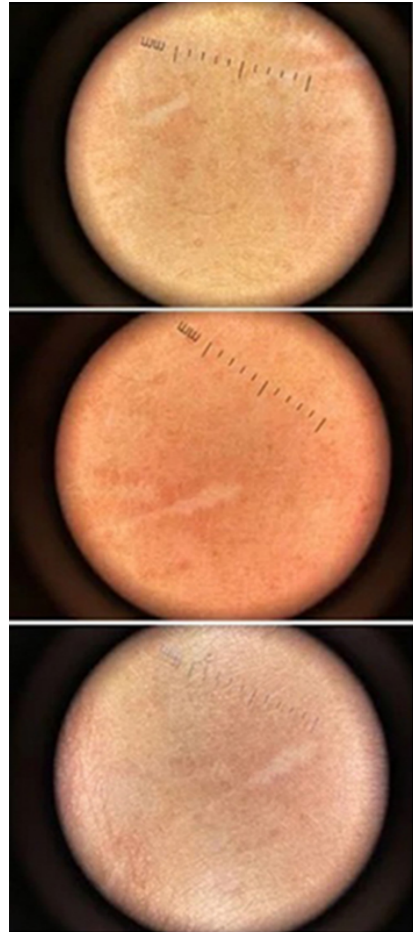
PHONE COVER ADAPTER
iPhone & Samsung phone cover for dermatoscope



BACK UP BATTERY
1000mAh Lithium ion battery for replacement



DERMATOSCOPE DE-3100



Features

- 10 x Magnification
- 32mm wide field of view
- Polarized, non-polarized, and amber light illumination
- Detachable protective glass
- Automatic shutdown
- Included adapter fits all phone
- All-metal housing

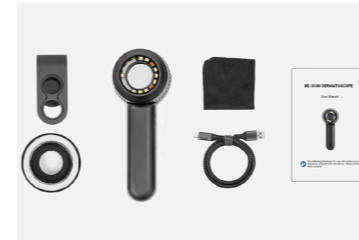
Technical Information

Material	Aluminum & Glass
Optical Design	All glass, 4 elements 3 groups, anti-reflection coating
Lens Diameter	32mm(front); 25mm(rear)
Magnification	10X
Distortion	5%
Polarization	4 LEDs white non polarized, 4 LEDs amber polarized, 8 LEDs white polarized
Resolution	300 LP/MM (Axis) 250 LP/MM (Edge)
LED Type	SMD LED beads
Battery Capacity	1000mAh Lithium ion
Charging	USB-C
Working Time	3-6 hours

Accessories DE-3100



UNIVERSAL PHONE ADAPTER
Save images of lesions on your smartphone



IN THE BOX
Relative accessories included in the package



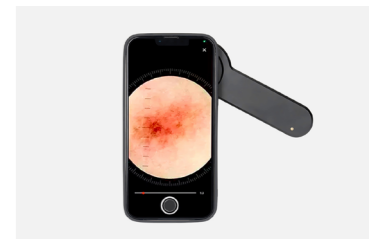
SMALL CONTACT PLATE
To detect difficulty access pigmented lesions



CAMERA ADAPTER
Save images of lesions on your camera



PHONE COVER ADAPTER
iPhone & Samsung phone cover for dermatoscope



BACK UP BATTERY
1000mAh Lithium ion battery for replacement



DERMATOSCOPE DE-400



Features

- 10 x Magnification
- 45mm wide field of view
- Polarized, non-polarized, and amber light
- Detachable protective glass
- Automatic shutdown
- Universal Phone Adapter
- 10-15mm Close Focus
- All-metal housing



Technical Information	
Material	Aluminum & Glass
Optical Design	All glass, 4 elements 4 groups, anti-reflection coating
Lens Diameter	45mm
Magnification	10X
Distortion	5%
Polarization	3 LEDs white non polarized, 9 LEDs white polarized
Resolution	300 LP/MM (Axis) 250 LP/MM (Edge)
LED Type	SMD LED beads
Battery Capacity	200mAh Lithium ion
Charging	USB-C
Working Time	90 minutes

DERMATOSCOPE DE-300



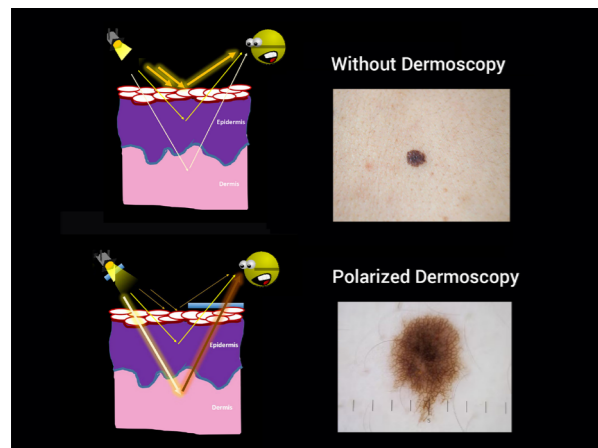
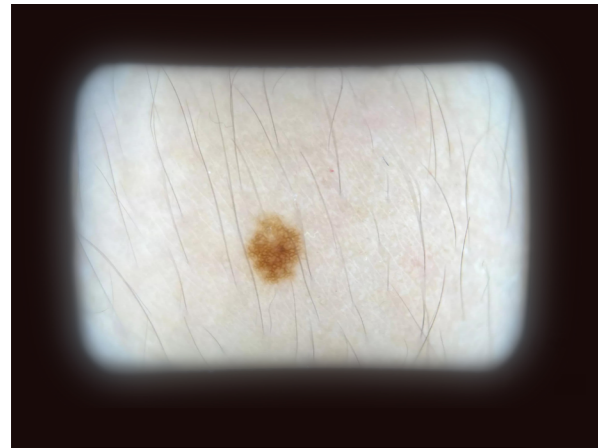
Features

- 6 x Magnification
- 20mm wide field of view (Aperture)
- Polarized light illumination
- Automatic shutdown
- Universal Phone Adapter
- All-metal housing



Technical Information	
Material	Aluminum & Glass
Optical Design	All glass, 2 elements 2 groups, anti-reflection coating
Lens Diameter	30mm
Magnification	6X
Distortion	8%
Polarization	2 LEDs white non polarized, 4 LEDs white polarized
Resolution	300 LP/MM (Axis) 250 LP/MM (Edge)
LED Type	SMD LED beads
Battery Capacity	200mAh Lithium ion
Charging	USB-C
Working Time	90 minutes

DERMATOSCOPE DE-200



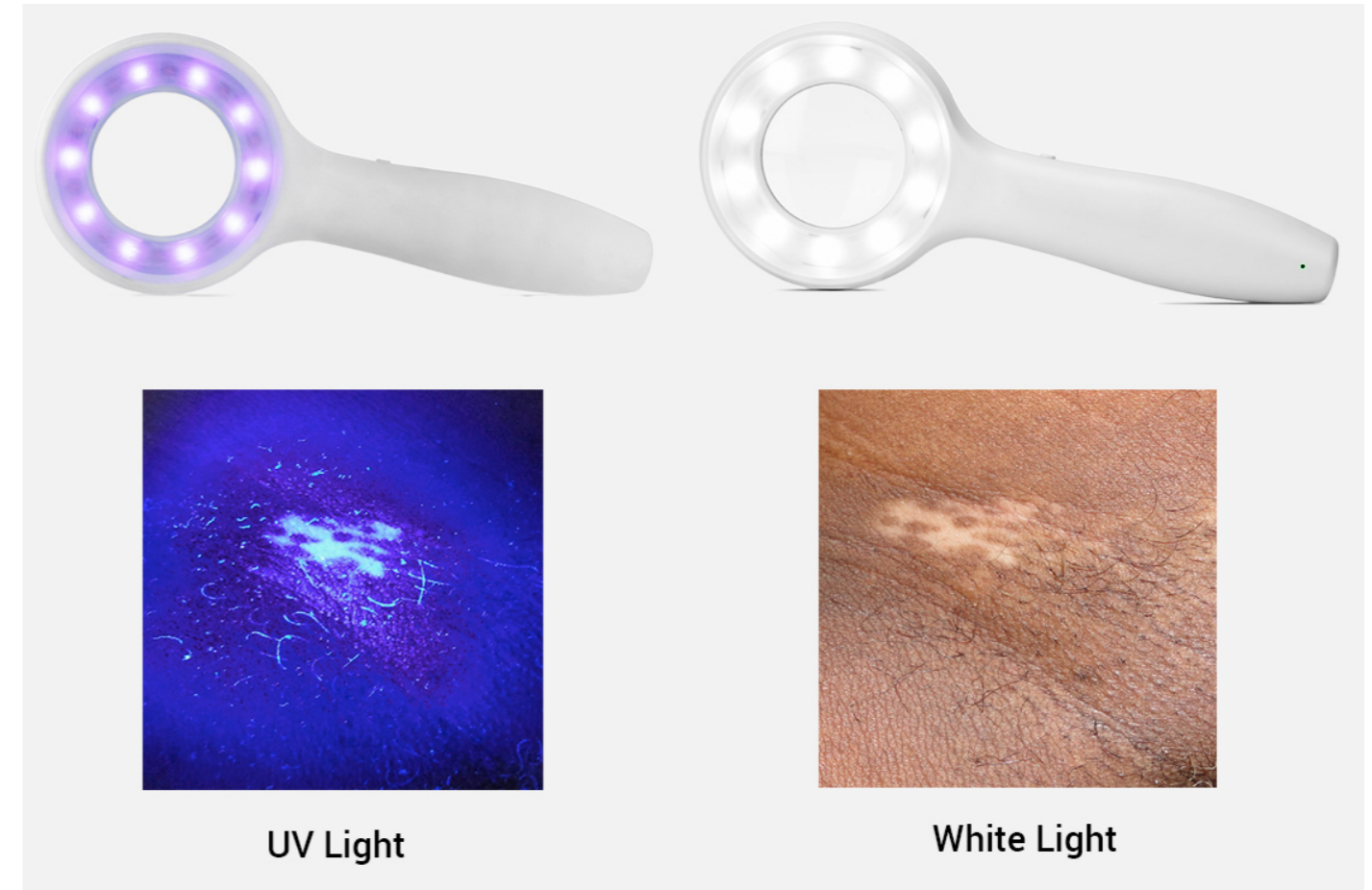
Features

- 6 x Magnification
- 20mm wide field of view
- Polarized light illumination
- Automatic shutdown
- Universal Phone Adapter
- All-metal housing

Technical Information

Technical Information	
Material	Aluminum & Glass
Optical Design	All glass, 2 elements 2 groups, anti-reflection coating
Lens Diameter	20mm
Magnification	6X
Distortion	8%
Polarization	2 LEDs white polarized
Resolution	300 LP/MM (Axis) 250 LP/MM (Edge)
LED Type	SMD LED beads
Battery Capacity	200mAh Lithium ion
Charging	USB-C
Working Time	90 minutes

WOODS LAMP DE-215



UV Light

White Light

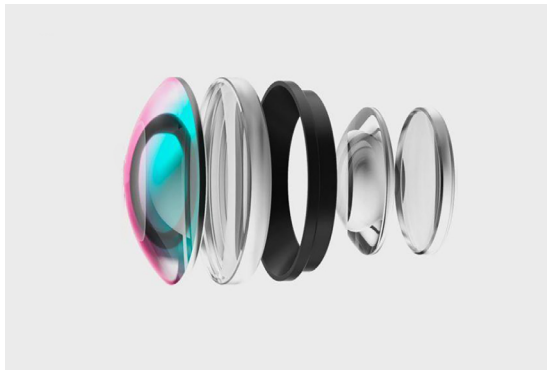
What It Has

- **365nm UV Light:** A Wood's lamp has broadband light sources that emit light at wavelengths between 320nm and 400nm, with a peak at 365nm.
- **4.5X Magnification:** Low distortion magnify
- **2000mAh Battery:** Offering up to 6 hours long time and stable diagnosis.

Specs

- Lens Diameter: 50mm
- Magnification: 4.5X
- Ultraviolet Wavelength: 365nm
- Radiation Intensity: 3.5 mW/cm²
- Battery Capacity: 2000mAh
- Charging: USB Type-C
- Working Time: 2-6 hours
- Dimension: 240mm*100mm*34mm(L*W*H)
- Weight: 166.5g

Why Choose Our Dermatoscope



Exceptional Lens Design

Designed by optics engineers with over 20 years of experience making high-end camera lenses. Carefully crafted coatings, and hand-finished glass from our precision factory



Made From Aerospace Grade Metal

It's made of aerospace-grade metal instead plastic body design. The curved shape of the handle fit comfortably in your hand and provide a smooth and intuitive user experience.

Affordable Price

Our goal was to bring affordable and top quality into one product, while making the device durable for long time usage.



CONTACT US

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Website: <http://www.iboolo.com>