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

UDI-DI 06923299016887

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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-000002066
Address: 36 Zonnehof Nootdorp
Telephone number: +31(0) 64 6571 005
Email: office@kingsmead-service.com

Basic UDI-DI details

Version 1 [Current] | Last update date: 2022-10-20

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

and/or remove medicinal product:	
Device model applicable:	Yes
Device model:	DE-3100
Name:	Dermatoscope

Tissues and cells

Presence of human tissues or cells, or their derivatives:	No
Presence of animal tissues or cells, or their derivatives:	No

Information on substances

Presence of a substance which, if used separately, may be considered to be a medicinal product:	No
Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma:	No

List of UDI-DIs for the Basic UDI-DI

UDI-DI details

Version 1 [Current] | Last update date: 2022-10-20

UDI-DI code:	06923299016887
Issuing Entity:	GS1

UDI-DI from another entity

UDI-DI from another entity (secondary) applicable:	No

Selected nomenclature codes

Code Z12040108 DERMATOSCOPES

Trade name

Trade name applicable:	Yes
Trade name:	Dermatoscope [EN]
Reference/Catalogue number:	DE-3100

Is the device directly marked?

Is the device directly marked?:	No
Quantity of device:	1

Type of UDI-PI

Serial number:	Yes
Manufacturing date:	Yes
Expiration date:	Yes
URL for additional information (as electronic instructions for use):	-
UDI-DI status:	On the EU market

UDI-DI characteristics

Clinical size

Clinical size applicable:	No

Labelled as single use

Labelled as single use:	No
Maximum number of reuses applicable:	No
Maximum number of reuses:	-

Need for sterilisation before use:	No
Device labelled as sterile:	No
Containing latex:	No

CMR/Endocrine disruptor

Labelled for presence of Carcinogenic, Mutagenic and toxic to Reproduction (CMR) substances of category 1A or 1B:	No
Labelled for presence of substance(s) with endocrine-disrupting properties:	No

Storage/handling conditions

Storage/handling conditions, if applicable:	Yes
Storage/handling condition #1:	(Type) OTHER * - (Description) Store the device in dry rooms and do not expose it to high temperatures. [EN]

Critical warnings or contra-indications

Critical warnings or contra-indications, if applicable:	No
Reprocessed single use device:	No
Intended purpose other than medical (Annex XVI):	No

Information on substances

Presence of a substance which, if used separately, may be considered to be a medicinal product:	Not applicable
Presence of a substance which, if used separately, may	Not applicable

be considered to be a medicinal product derived from human blood or human plasma:	

Market information

Version 1 [Current] | Last update date: 2022-10-20

Member State of the placing on the EU market of the Device:	Austria

Member States where device is or is to be made available on the market:	**Country**	**From**	**To**
	Austria	-	-
	Belgium	-	-
	Czech Republic	-	-
	Denmark	-	-
	Finland	-	-
	France	-	-
	Germany	-	-
	Greece	-	-
	Hungary	-	-
	Ireland	-	-
	Italy	-	-
	Luxembourg	-	-
	Netherlands	-	-
	Poland	-	-
	Portugal	-	-
	Slovakia	-	-
	Slovenia	-	-
	Spain	-	-
	Sweden	-	-
	United Kingdom (Northern Ireland only)	-	-

Clinical Investigation(s)

Clinical Investigation

Clinical Investigation, if applicable:	No

Certificate information