ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 002145 0004 Rev. 00

Manufacturer:

Shenzhen IMDK Medical Technology CO., Ltd
904, 9F
Guangming Tianan Cloud Park Building
255 Zhenmei Road, Zhenmei Community
Xinhu Street
Guangming District
518107 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000024290

Authorized Representative:

MedNet EC-REP GmbH
Borkstraße 10, 48163 Münster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 002145 0004 Rev. 00

Report No.: GZ2228303

Valid from: 2023-11-24
Valid until: 2028-11-23

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-11-24

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 002145 0004 Rev. 00

Classification:	Class IIa
Device Group:	Z1203020408 - PULSE OXIMETERS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2023-11-24	GZ2228303	Initial issuance

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TÜV®

EU DECLARATION OF CONFORMITY

Manufacturer Shenzhen IMDK Medical Technology Co., Ltd.
904, 9F, Guangming Tianan Cloud Park Building, 255 Zhenmei Road, Zhenmei Community, Xinhu Street, Guangming District,518107, Shenzhen，PEOPLE'S REPUBLIC OF CHINA.

Single Registration Number (SRN): CN-MF-000024290

Authorized Representative: MedNet EC-REP GmbH
Borkstrasse 10 · 48163 Muenster · Germany

SRN Authorized Representative: DE-AR-000000002

Swiss Representative: MedNet Swiss GmbH
D4 Platz 4,6039 Root D4, Switzerland

SRN Authorized Representative: CHRN-AR-20000730

Product Identification

Product/Trade Name:	Pulse oximeter
Model:	C101H1, C101A2, PO-A2AO, PO-A2AT, PO-A3AO, PO-H1AO, PO-B1AO, PO-C5AO, PO-C5AT, PO-C6AO, PO-C6AT
Basic UDI-DI:	697391294101PO8Z

Product Code

GMDN Code:	45607
GMDN Term:	Oximeter
EMDN Code/CDN code:	Z1203020408
EMDN Term/CDN Term:	PULSE OXIMETERS

Classification

Risk Class:	class IIa, Rule 10 (according to rule 10 of Annex VIII Medical Device Regulation (EU) 2017/745)

Conformity assessment Route: Annex IX chapter I + chapter III of Regulation (EU) 2017/745

We (Shenzhen IMDK Medical Technology Co., Ltd) declare that the above medical device is at our sole responsibility the state medical device (Model: C101H1, C101A2, PO-A2AO, PO-A2AT, PO-A3AO, PO-H1AO, PO-B1AO, PO-C5AO, PO-C5AT, PO-C6AO, PO-C6AT) in conformity with the following legislation(s):

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices

The conformity of the quality management system according to Annex IX and Article 52 is certified by the following notified body:

TÜV SÜD Product Service GmbH
Zertifizierstellen Ridlerstraße 65
80339 MÜNCHEN
Germany

The identification number of the notified body for implementation of the procedure set out in Annex IX and Article 52 to the above regulation is: 0123
Certificate number of issued certificate: G10 002145 0004 Rev.00
Reference to Common Specifications: /

This declaration of conformity is issued under the sole responsibility of Shenzhen IMDK Medical Technology Co., Ltd

This declaration supersedes any declaration issued previously for the same product.

Every article we sell is covered by a technical file. Technical files are provided to the European Authorized representative and kept up to date by us.

Place and date <Shenzhen, 2026/02/04>

Signature 

Name Yuan Xia

Position Person Responsible for Regulatory Compliance

Signature 

Name ChangChun Xia

Position General Manager

JACK Vinger Pulse Oximeter - Gebruiksaanwijzing

Model: C101A2 | EAN: 8721516448286 | Merk: JACK | Verkoper: Global Bay

1. Bedoeld Gebruik

De JACK Vinger Pulse Oximeter is een draagbaar, niet-invasief apparaat bedoeld voor het meten van de zuurstofsaturatie in arterieel hemoglobine (SpO2) en de polsslag bij volwassenen thuis en in ziekenhuisomgevingen. De patiënt kan zelf de gebruiker zijn. Het apparaat is niet geschikt voor continue bewaking op lange termijn.

2. Inhoud van de Verpakking

1x Pulse Oximeter C101A2
2x AAA 1.5V alkaline batterijen
1x Draagkoord
1x Opbergtasje
1x Gebruiksaanwijzing

3. Gebruik

3.1 Batterijen plaatsen:

1. Open het batterijklepje.
2. Plaats 2x AAA batterijen volgens + / - markering.
3. Sluit het klepje.

3.2 Meting uitvoeren:

1. Steek één vinger volledig in de siliconen opening (nagel naar boven).
2. Druk op de aan/uit-knop aan de voorkant.
3. Blijf stil zitten gedurende 8-10 seconden tot de waarden stabiel zijn.
4. Lees SpO2 en PR (hartslag) af. Druk kort op de knop om de weergaverichting te wijzigen (4 richtingen).
5. Het apparaat schakelt automatisch uit na 8 seconden zonder signaal.

4. Technische Specificaties

Parameter	Specificatie
Model	C101A2
Meetbereik SpO2	35% ~ 99%
Nauwkeurigheid SpO2	80-99%: ±2%, 70-79%: ±3%
Hartslagbereik	30 bpm - 240 bpm
Resolutie	SpO2: ±1%, PR: ±1 bpm
Display	OLED/TFT, 2-kleuren
Voeding	2x AAA 1.5V alkaline, ca. 8 uur continu gebruik
Afmetingen	60 x 38 x 33 mm
Gewicht	ca. 50g (zonder batterijen)
Bescherming	IP22
Werktemperatuur	+5°C ~ +40°C, 15%-95% RH
Opslagtemperatuur	-20°C ~ +55°C
Levensduur	3 jaar
Lichtbron	Rood 660nm / Infrarood 905nm, 5.0mW

Classificatie	Medisch hulpmiddel Klasse IIa, Regel 10, MDR (EU) 2017/745

5. Waarschuwingen & Veiligheid

- Raadpleeg altijd uw arts. Dit apparaat is geen basis voor medische beslissingen.
- Niet gebruiken in MRI-omgeving of in aanwezigheid van brandbare anesthetica.
- Nagellak of kunstnagels kunnen de meting beïnvloeden. Vinger moet schoon zijn.
- Niet continu langer dan 2 uur op dezelfde vinger gebruiken.
- Kleine onderdelen - buiten bereik van kinderen houden.
- Batterijen niet opladen. Lege batterijen direct vervangen om lekkage te voorkomen.

6. Onderhoud en Reiniging

Reinig de rubberen binnenkant met 70% isopropanol voor en na elk gebruik. Geen vloeistof in het apparaat laten komen. Droog bewaren. Geen agressieve reinigingsmiddelen gebruiken.

7. Problemen Oplossen

Geen SpO2 zichtbaar -> Vinger opnieuw plaatsen, stil blijven zitten, batterijen controleren. Scherm blijft uit -> Batterijen vervangen. Zwak signaal -> Lage doorbloeding, koude handen - handen opwarmen.

8. Afvoer

WEEE. Niet bij huishoudelijk afval. Batterijen en apparaat gescheiden inleveren bij gemeentelijk inzamelpunt volgens Richtlijn 2012/19/EU. Batterijen symbool: doorgekruiste afvalbak.

9. Fabrikant & Vertegenwoordiging

Fabrikant: Shenzhen IMDK Medical Technology CO., Ltd, No.4 Jinhuacheng, Guwei 1st Road, Xixiang Street, Baoan District, 518102 Shenzhen, China. SRN: CN-MF-000024290
EU Authorized Representative: MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany. SRN: DE-AR-000000002, Notified Body 0123 TÜV SÜD.
Distributeur / Verkoper: Global Bay
Basis UDI-DI: 697391294101PO8Z
Versie: V1.2 | 2025-07-17 | Doc No: IMDK/RD-E-PO-01-005

JACK Finger Pulse Oximeter - User's Manual

Model: C101A2 | EAN: 8721516448286 | Brand: JACK | Seller: Global Bay

1. Intended Use

The JACK Finger Pulse Oximeter is a portable non-invasive device intended for measuring arterial hemoglobin oxygen saturation (SpO2) and pulse rate of adults in hospitals, hospital-type facilities and home environments. The patient can be the operator. Not suitable for long-term continuous monitoring.

2. Package Contents

1x Pulse Oximeter C101A2
2x AAA 1.5V alkaline batteries
1x Lanyard
1x Storage pouch
1x User's Manual

3. Operation

3.1 Battery installation:

Open battery cover, insert 2x AAA batteries with correct polarity, close cover.

3.2 Measurement:

1. Insert one finger fully into silicone hole with nail surface upward.
2. Press power button on front panel.
3. Keep finger still for 8-10 seconds until readings stabilize.
4. Read SpO2 and Pulse Rate. Short press button to change display direction (4 directions).
5. Device auto powers off after 8 seconds without signal.

4. Specifications

Parameter	Specification
Model	C101A2
SpO2 Range	35% ~ 99%
SpO2 Accuracy	80-99%: ±2%, 70-79%: ±3%
Pulse Rate Range	30 bpm - 240 bpm
Resolution	SpO2: ±1%, PR: ±1 bpm
Display	OLED/TFT, two-color
Power	2x AAA 1.5V alkaline, approx. 8h continuous
Dimensions	60 x 38 x 33 mm
Weight	approx. 50g (without batteries)
Water Protection	IP22
Operating Temp	+5°C ~ +40°C, 15%-95% RH
Storage Temp	-20°C ~ +55°C
Service Life	3 years
Light Source	Red 660nm / Infrared 905nm, 5.0mW
Classification	Medical Device Class IIa, Rule 10, MDR (EU) 2017/745

5. Warnings

- Always consult physician. Do not use as sole basis for medical decisions.
- Do not use in MRI environment or flammable atmosphere.
- Nail polish / false nails may cause inaccurate readings.
- Do not monitor continuously >2 hours on same finger.
- Small parts - keep away from children.
- Do not attempt to recharge alkaline batteries.

6. Maintenance

Clean rubber inside with 70% isopropanol before and after each test. Keep dry. Do not spill liquid into device.

7. Troubleshooting

No SpO2 - reinsert finger, stay still, check batteries. No power - replace batteries. Weak signal - low perfusion, warm hands.

8. Disposal

WEEE Directive 2012/19/EU. Do not dispose as domestic waste. Dispose batteries and device separately at collection points.

9. Manufacturer

Manufacturer: Shenzhen IMDK Medical Technology CO., Ltd, No.4 Jinhuacheng, Guwei 1st Road, Baoan, 518102 Shenzhen, China. SRN: CN-MF-000024290
EU REP: MedNet EC-REP GmbH, Borkstr. 10, 48163 Muenster, Germany. SRN: DE-AR-000000002, Notified Body 0123 TÜV SÜD
Seller: Global Bay
Basic UDI-DI: 697391294101PO8Z
Doc No: IMDK/RD-E-PO-01-005 Ver V1.2 2025-07-17

EU Legal Guarantee Notice & GARAN Label / Wettelijke Garantie Informatie

Verkoper / Seller:	Global Bay
Product:	JACK Vinger Pulse Oximeter - Saturatiemeter - Professionele Zuurstofmeter met Hartslagm
Model:	C101A2
EAN:	8721516448286
Fabrikant:	Shenzhen IMDK Medical Technology CO., Ltd (MDR Certified Class IIa)
EU Authorized Representative:	MedNet EC-REP GmbH, Borkstr. 10, 48163 Muenster, Germany

GARAN - EU Geharmoniseerd Label
Wettelijke garantie: 2 jaar
Commerciële duurzaamheidsgarantie: Niet van toepassing / Not provided
Legal Guarantee: 2 years

1. Wettelijke Garantie (Legal Guarantee)

Dit product valt onder de wettelijke garantie van 2 jaar zoals beschreven in de EU-richtlijn 2019/771. De verkoper, Global Bay, is aansprakelijk voor elk gebrek aan overeenstemming dat bestaat op het moment van levering en dat zich binnen 2 jaar na levering manifesteert. Consumenten hebben recht op kosteloos herstel of vervanging conform artikel 13 van de richtlijn.
This product is covered by the 2-year legal guarantee in accordance with EU Directive 2019/771. Global Bay is liable for any lack of conformity existing at the time of delivery and becoming apparent within 2 years.

2. Commerciële Duurzaamheidsgarantie (Commercial Durability Guarantee)

Voor dit product wordt geen aanvullende commerciële duurzaamheidsgarantie verleend die langer duurt dan de wettelijke garantie, zoals bedoeld in artikel 17 van Richtlijn (EU) 2019/771. De GARAN-label geeft daarom aan: Wettelijke garantie 2 jaar – Geen aanvullende commerciële duurzaamheidsgarantie.
No additional commercial guarantee of durability within the meaning of Article 17 of Directive (EU) 2019/771 is provided beyond the legal guarantee. Therefore the GARAN label states: Legal guarantee 2 years – No additional commercial durability guarantee.

3. Fabrieksgarantie / Manufacturer Warranty

Fabrieksgarantie termijn: 2 jaar. Reparatie type: Vervanging (Omruilen) via verkoper. De fabrieksgarantie dekt fabricagefouten en materiaalgebreken bij normaal gebruik. Batterijen en schade door verkeerd gebruik vallen buiten de garantie.
Manufacturer warranty: 2 years. Repair type: Replacement via seller.

4. Contact & Aftersales

Voor garantieclaims neem contact op via bol.com berichten of e-mail met vermelding van EAN 8721516448286 en bestelnummer. Bewaar het aankoopbewijs.
Manufacturer: Shenzhen IMDK Medical Technology CO., Ltd, No.4 Jinhuacheng, Guwei 1st Road, Baoan District, Shenzhen, China.
EU REP: MedNet EC-REP GmbH, Borkstr. 10, 48163 Muenster, Germany.

Dit document voldoet aan het geharmoniseerde GARAN-label model van de EU zoals beschreven op https://europa.eu/youreurope/business/selling-in-eu/consumer-contracts-guarantees/eu-legal-guarantee-notice-and-garan-label/index_nl.htm

Datum: 12-10-2026 | Document voor EAN 8721516448286 | Verkoper: Global Bay | Handtekening verkoper: _____