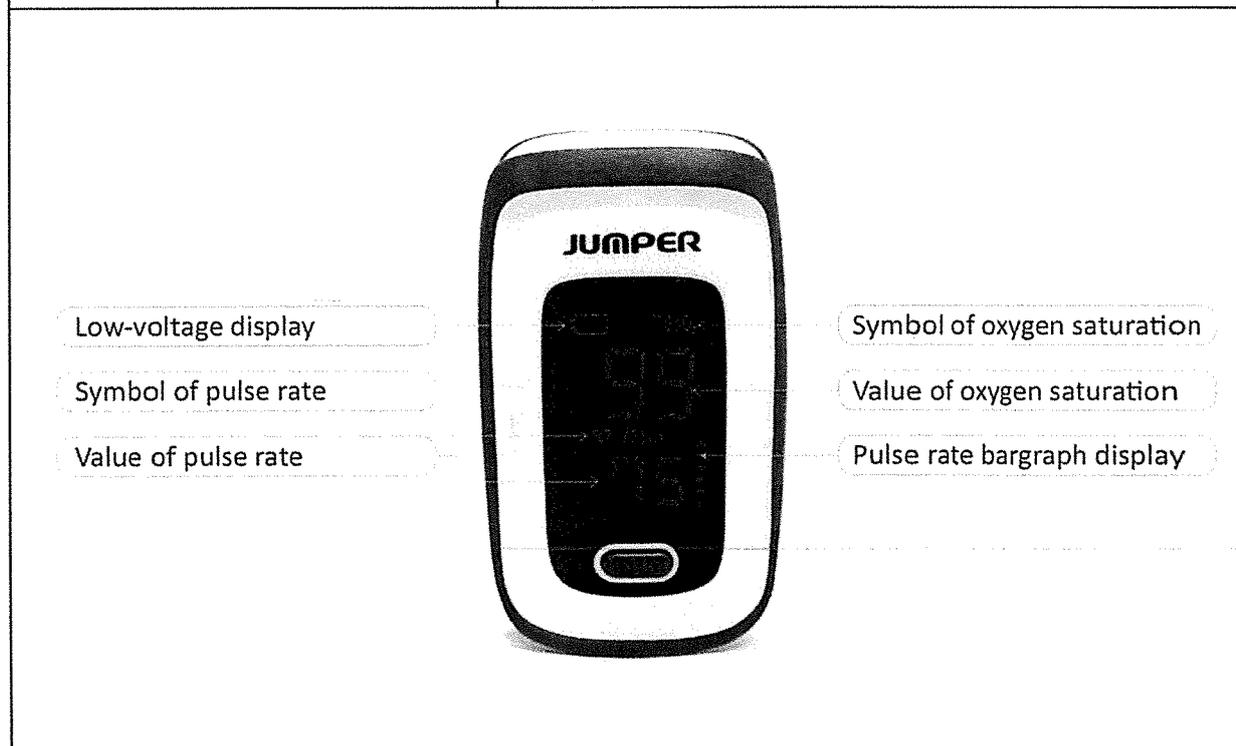


SCHEMA TECNICA

COD: JPD-500E(LED)

Produttore	Jumper Medical D Building No 71 Xintian Road Fuyong Street Baoan Shenzhen Guangdong China 518103
Descrizione prodotto	Pulsossimetro da dito
Materiali di produzione	ABS (struttura) Componenti elettrici (metalli, plastiche, silicone)
Codice Prodotto	JPD-500E(LED)
Confezionamento	1 pezzo
Display	Schermo LED HED
Alimentazione	AAA 2X - DC 3 V



Unità misurate	Frequenza di pulsazione SpO2
Accuratezza	SpO2: 70%-100%, $\pm 2\%$ Range di pulsazioni 25-250bpm ± 2 bpm
Risoluzione	Frequenza di pulsazione - 1bpm SpO2 - 1%
Indicazioni	Indicazione livello basso delle batterie Promemoria limite di valore Segnali acustici

SCHEDA TECNICA

Range ambientali di funzionamento	5° - 40° C Umidità relativa 15% - 80% - non condensante Pressione atmosferica 70 – 106 kPa
Stoccaggio e trasporto	-10° - 50° C Umidità relativa 10% - 93% - non condensante Pressione atmosferica 50 – 106 kPa
Range di applicazione	Adulti - Adolescenti
Peso e dimensioni	50 gr con le batterie – 62 x 37 x 32 mm
Conformità e certificazioni	CE 93/42 EN 980 – EN ISO 10993-175710 – EN 60601-1/1-2/1-4/1-6
Presenza di Lattice	-
Accessori	2 batterie AAA Borsa protettiva Laccio per il fissaggio IFU
Classificazione Prodotto	Dispositivo Medico di Classe IIa
CND	C900301
RDM	1682781
Marchio CE	N. 0482 - Certificato N. 7111gb410191229



Certification Medical Only

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

Shenzhen Jumper Medical Equipment Co., Ltd.
D Building, No. 71, Xintian Road, Fuyong Street,
Baoan, Shenzhen, Guangdong
China

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2019-12-20

Expiry date: 2024-05-27

Report No.: 7111FS10F

Process No.: QS - 7111

Certificate No.: 7111GB410191220

Hamburg, 2019-12-20

MEDCERT Certification Body
(Markus Bianchi)

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To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15



Certification Medical Only

Appendix of EC Certificate of Conformity

Process No.: QS-7111

Certificate No.: 7111GB410191220

List of products / product categories included in the scope of certificate

- Fetal dopplers
- Fetal/maternal monitors
- Multi parameter patient monitors
- Pulse oximeters
- Infrared thermometers
- Electronic blood pressure monitors

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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Medizinprodukten
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ZLG-BS-237.10.15

Certificate

The certification body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**Shenzhen Jumper Medical Equipment Co., Ltd.
D Building, No. 71, Xintian Road, Fuyong Street,
Baoan, Shenzhen, Guangdong
China**

has introduced, applies and maintains a quality management system in the area of:

**Design and development, manufacture and distribution of products as
listed in the appendix**

The conformity of this quality management system to the requirements of the below mentioned
standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2019-12-20
Expiry date: 2022-09-28

Report No.: 7111FS10F
Procedure No.: QS-7111
Certificate No.: 7111GB445191220

Hamburg, 2019-12-20

MEDCERT Certification Body
(Markus Bianchi)

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MEDCERT is a DAKKS accredited management systems
certification body



Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

Appendix of certificate

Procedure No.: QS - 7111

Certificate No.: 7111GB445191220

List of products included in the scope of certificate

- **Fetal Dopplers**
- **Fetal/Maternal Monitors**
- **Multi-Parameter Patient Monitors**
- **Pulse Oximeters**
- **Infrared Thermometers**
- **Electronic Blood Pressure Monitors**

– End of list –

This appendix is integral part of the above-referenced certificate.
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Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

**KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE
DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA**

Name und Adresse der Firma
Nom et adresse de l'entreprise
Nome e indirizzo della ditta
Name and address of the firm

Shenzhen Jumper Medical Equipment Co., Ltd
D Building, No. 71, Xintian Road, Fuyong Street
Bao'an District, Shenzhen, 518102, China

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que /Dichiariamo sotto nostra responsabilità che / We declare under our sole responsibility that

das Medizinprodukt
le dispositif médical
the medical device
il dispositivo medico

PULSE OXIMETER JPD-500E(LED); INFRARED THERMOMETER JPD-FR202

Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stückzahl Nom, type ou modèle, numéro de lot ou série, év. source et nombre d'exemplaires Nome, tipo o modello, numero di lotto o di serie, ev. fonte e numero di esemplari/Name, type or model, batch or serial number, possibly sources and number of items

der Klasse / de la classe / della classe / of class

Class II a, Rule10

Nach Anhang IX der Richtlinie 93/42/EWG / selon l'annexe IX de la directive 93/42/EEC /secondo l'allegato IX della direttiva 93/42/EEC / according to annex IX of direct. 93/42/EEC

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG (od. 90/385/EWG) entspricht, die anwendbar sind/
remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/EEC (ou 90/385/EEC) qui le concernent
/ soddisfa tutte le disposizioni della direttiva 93/42/EEC (opure 90/385/EEC) che lo riguardano /meets all the provisions of the directive 93/42/EEC (or 90/385/EEC) which apply to it.

Angewandte harmonisierte Normen,
nationale Normen oder andere
normative Dokumente
Normes harmonisées, normes
nationales et autres documents
normatifs appliqués
Norme armonizzate o nazionali
applicative,altri documenti normativi
applicati
Applied harmonised standards, national
standards or other normative
documents

EN 980: 2008 / EN 1041:2008 / EN ISO 14971:2012
EN ISO 10993-1:2009 / EN ISO 10993-5:2009 / EN ISO 10993-10:2013
EN 60601-1:2006+A1:2013
EN 60601-1-2:2007+AC:2010 / EN 60601-1-4:1996+A2:1999 /
EN 60601-1-6:2010

Konformitätsbewertungsverfahren
Procédure d'évaluation de la conformité
Procedimento di valutazione della
conformità
Conformity assessment procedure

This declarraiaon of conformity is based on the European Medical Device Directive 93/42/EEC, Annex II

Konformitätsbewertungsstelle (falls beigezogen)
Organe resp. de l'évaluat. de la conformité (si consulté)
Organo incaric. della valutaz. della conform. (se consultato)
Notified Body (if consulted)

MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg
Weikang Ltd
Suite B, 29 Harley Street , London W1G 9QR, UK

2020-02-22 SHENZHEN

Ort, Datum / Lieu, date / Luogo, data / Place, date

Manufacture: Shenzhen Jumper Medical Equipment Co., Ltd.

Name und Funktion / Nom et fonction
/Nome e funzione / Name and function

Natasha

Natasha Li

