EC Declaration of Conformity

MANUFACTURER: Shenzhen Witleaf Medical Electronics co., Ltd.

Room 1201, Building 1, Senyang Electronic Technology Park, West Area, Guangming Hi-tech Park, Tianliao Community, Yutang Street, Guangming District,518132 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

1.MEDICAL DEVICE: Patient Monitor
Model: XH-80,XH-90,W12,W15,E12,E15,E10,L15,L12,L10

CLASSIFICATION: CLASS IIb, RULE 10
CONFORMITY ASSESSMENT ROUTE:MDD 93/42/EEC ANNEX II without 4

WE, Shenzhen Witleaf Medical Electronics co., Ltd., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
WE, THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC

NOTIFIED BODY:	TÜV SÜD Product Service GmbH Ridlerstraße 65·80339 Munich·Germany
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	G1 005136 0002 Rev.00
VALID UNTIL:	2024-04-14
EC REP EUROPEAN REPRESENTATIVE:	Zug Medical Systems 291 Rue Albert Caquot,CS40095 06902 Sophia Antipolis, France

START OF CE-MARKING:

PLACE, DATE OF DECLARATION:	SHENZHEN, 2023-01-16
SIGNATURE:	*NAME:* [signature] *POSITION: (MANAGEMENT REPRESENTATIVE)*

Digitally signed by Jighili Tatiana
Date: 2023.06.20 12:24:01 EEST
Reason: MoldSign Signature
Location: Moldova

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
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 005136 0002 Rev. 01

Manufacturer:

Shenzhen Witleaf Medical Electronics Co., Ltd.
13/F-B2, Block 1
Senyang Science Park
No.7 Road, West District of High-Tech Park
Guangming District
518132 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Patient Monitor, Rapid Intervention Capnograph, Fingertip Pulse Oximeter, Handheld Pulse Oximeter**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. 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:G1 005136 0002 Rev. 01

Report No.: GZ2035701

Valid from: 2021-04-22
Valid until: 2024-04-14

Date, 2021-04-22

Christoph Dicks
Head of Certification/Notified Body

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 005136 0001 Rev. 02

Holder of Certificate: **Shenzhen Witleaf Medical Electronics Co., Ltd.**
Room 1201, Building 1
Senyang Electronic Technology Park
West Area, Guangming Hi-tech Park
Tianliao Community, Yutang Street
Guangming District
518132 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Patient Monitor, Rapid Intervention Capnograph, Fingertip Pulse Oximeter, Handheld Pulse Oximeter**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 005136 0001 Rev. 02

Report No.: GZ2135701

Valid from: 2022-06-01
Valid until: 2025-04-14

Date, 2022-06-01

Christoph Dicks
Head of Certification/Notified Body

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 005136 0001 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Shenzhen Witleaf Medical Electronics Co., Ltd.
Room 1201, Building 1, Senyang Electronic Technology Park, West Area, Guangming Hi-tech Park, Tianliao Community, Yutang Street, Guangming District, 518132 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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