*Anexa nr. 1*
*La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE*

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

**NOTIFICARE**
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. TR-5 din 20.06.2023

Solicitantul TRIUMF MOTIV SRL, cu sediul or. Chișinău str. Grenoble 193
(adresa)
_____, tel./fax: 022768462, e-mail triumf.motiv@mail.ru,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Patient monitor with 15.6 inch touch screen - W15

Se anexează următoarele acte:

DECLAȚIE DE CONFORMITATE CE
CERTIFICATUL DE CONFORMITATE CE
Scrisoare de autorizare de la producător

Data 20.06.2023 Semnătura _____

**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

| | |
|---|---|
| Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului | |
| Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării) | |
| Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului | |
| Semnătura persoanei responsabile | |

Digitally signed by Jighili Tatiana
Date: 2023.06.20 12:24:38 EEST
Reason: MoldSign Signature
Location: Moldova

*Anexa nr. 2*
*La Procedurile administrative pentru notificarea*
*dispozitivelor medicale care dețin marcajul CE*

Către Agenția Medicamentului și Dispozitive Medicale

**DECLARAŢIE PE PROPRIE RĂSPUNDERE**

Solicitant: _____TRIUMF MOTIV SRL_____, cu sediul _____or. Chișinău str. Grenoble 193_____,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Patient monitor with 15.6 inch touch screen - W15

**Sunt autentice și corespund realității.**

*Numele, prenumele şi funcţia Jighili Tatiana, Administrator*
*Semnătura* _____

*Data _20.06.2023___*

**Shenzhen Witleaf Medical Electronics Co., Ltd**
Room 1201, Building 1 Senyang Electronic Technology Park West Area, Guangming Hitech Park Tianliao Community, Yutang Street Guangming District 518132 shenzhen, People's Republic of China. Fax: 0086-0755-21384138-802
Website: www.szwitleaf.com Contact: Holly Email: holly@szwitleaf.com

# LETTER OF AUTHORIZATION

Date: 19th Jun. 2023

To Whom It May Concern:

Hereby, we

Shenzhen Witleaf Medical Electronics Co., Ltd.,

Address: Room 1201, Building 1 Senyang Electronic Technology Park West Area, Guangming Hitech Park Tianliao Community, Yutang Street Guangming District 518132 shenzhen, People's Republic of China.

Certify that:

Triumf Motiv SRL

Address: Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1

Tel: (+373 22) 76 84 62, 76 88 41

as our authorized representative and distributor on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand Witleaf in your country.

This letter of authorization remains valid for five years, starting from 19th Jun. 2023 and expiring on 19th Jun, 2028.

Name: Eden Liu

Title: General Manager

Signature:

SHENZHEN WITLEAF MEDICAL ELECTRONICS CO., LTD. 深圳市惟拓力医疗电子有限公司

Shenzhen Witleaf Medical Electronics Co., Ltd.

# 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<br>Ridlerstraße 65·80339 Munich·Germany |
| *IDENTIFICATION NUMBER* | 0123 |
| (EC) CERTIFICATE(S): | G1 005136 0002 Rev.00 |
| VALID UNTIL: | 2024-04-14 |
| EC REP<br>EUROPEAN REPRESENTATIVE: | Zug Medical Systems<br>291 Rue Albert Caquot,CS40095 06902 Sophia Antipolis, France |

START OF CE-MARKING:

| | |
|---|---|
| PLACE, DATE OF DECLARATION: | SHENZHEN, 2023-01-16 |
| SIGNATURE: | *NAME:* 吴翔 |
| | *POSITION: (MANAGEMENT REPRESENTATIVE)* |

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

TÜV®

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


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
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

.


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

# **W12/W15 Series** Patient Monitor

Intensive care/Sub-intensive care

12.1inch | 15.6inch

## Overview

The W12/W15 series patient monitor series are designed to meet daily clinical needs and seamlessly integrate into the hospital workflow. Modular design,Module interface can meet the needs of different parameters according to the clinical choice module.A variety of monitor models have more and more accurate practical clinical application values. In acute care, patient monitors must be reliable, easy to use, have advanced parameters, and allow access to data when needed. When transporting patients, the equipment should be easy to carry. The W12/W15 series of patient monitors are lightweight, powerful, and intuitive in user interface. They are the best choice for acute, in- and out-of-hospital transfers.

- HD Display
- Touch Screen
- Silence
- Intelligent Setting
- Easy Clean
- More Readable

For more information, please contact us: **sales@szwitleaf.com**

Witleaf

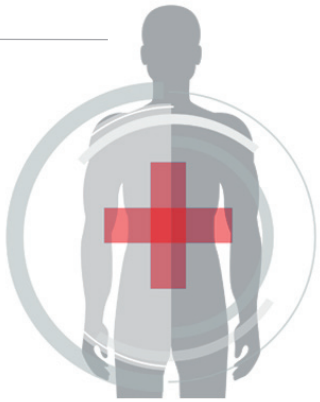
# Features

- The monitor adopts a modular design and a compact structure to meet the needs of various different parameter detections. It is suitable for adults, children and newborns.
- Standard parameters: SpO2, 12leads ECG, PR, HR, RESP, NIBP,2*TEMP.
- Optional parameters: EtCO2, 2*IBP, CO.
- 12.1inches/15.6inches colour LED screen with touch screen and /or rotator knob.
- Upgradable module is interchangeable (plug and play type).
- Capable to visualize 6 or more waveform. Support colour coding for different waveform.
- ST segment analysis with ST trend with continuous display of ST value on screen.
- Multiple screen layout to view big font size in numeric and waveform.
- Trending facilities for upto 360 hours of both graphical & numerical along with eventreview facility for all parameters and full waveform disclosure facility.
- Different visual alarm with colour coding and audible alarms for variousparameters with three levels of volume adjustment.
- Support HL7 protocol to access the central workstation Energy-saving, low-power design, extending battery life Configure noise reduction fan to ensure a quieter and cleaner environment Arrhythmia detection and analysis in various leads.
- A inbuilt battery backup of 4 hours.

EEG Ai

Resp CO2
AG

ECG SPO2
IBP/NIBP TEMP
PR



EEG and Ai Monitor Optimizing Anesthesia Delivery with Ai™ Monitoring

Patented CapnoSET and TiniStream technology

Excellent ECG analysis and Anti-motion NIBP & SPO2 Algorithm

## Multi-scenario application: Intensive care/Sub-intensive care

Plug-in Modular

- > Sidestream CO2+2IBP+CO
- > Sidestream CO2+2IBP
- > Sidestream CO2+EEG Wave
- > Sidestream CO2+Ai(Depth of anesthesia)
- > Sidestream CO2
- > Mainstream CO2
- > TiniStream CO2
- > 2 IBP+CO
- > Ai(Depth of anesthesia)
- > 2 IBP
- > EEG wave
- > CO

## Cential Monitoring System

Cential Monitoring System supports up to 64 beds or 64 patients across clinical units at the same time.

72 hours of 64-channel holographic physiological waveform storage and review.

Provides review of up to 240 hours trend data storage, 720 alarm events per beds.

Bi-directional communication with W12/W15 Series monitors for enhanced patient care.

W15

W12

x64*

## Physical Parameter

Dimensions : 15.6 inch (38cm*15cm*30cm)
12.1 inch (30cm*15cm*30cm)

Weight : 5.0kg (Including battery,built-in module)

Screen size:12.1inch and 15.6inch


## Specifications

### SPO2

SPO2 Range: 0~100%

SPO2 Accuracy : 70~100%,±2% <70%,Undefined

PI Range : 0~20%

PVI Range : 0.001%

PR Range : 25-250bpm

PR Accuracy : ±2bpm or ±2%(whichever is greater)

### ECG

ECG Range : 0.15~5.5mV

ECG Resolution : 2.36uV/LSB

HR Range : 15~300bpm(adult) 15~350bpm(child/neonate)

HR Accuracy : ±1bpm or ±1% (whichever is greater)

RR Range : 0~120bpm

RR Accuracy : 15~120rpm : ±2rpm or ±2% <15rpm:Undefined

### TEMP

| | |
|---|---|
| Range | 0-50°C |
| Accuracy | ±0.1°C |
| Resolution | 0.1°C |

## NIBP

| | |
|---|---|
| Pressure Range | 0~300mmHg |
| Pressure Accuracy | ±2mmHg or ±1% of reading (take thelarger value) |
| Resolution | 1mmHg |
| SYS Range | Adult:40-270mmHg Pediatric:40-200mmHg Neonate:40-130mmHg |
| DIA Range | Adult:10-210mmHg Pediatric:10-162mmHg Neonate:10-90mmHg |
| Mean Range | Adult:20-230mmHg Pediatric:20-170mmHg Neonate:20-100mmHg |
| Accuracy | The mean deviation<±5mmHg The standard deviation<8mmHg |

## IBP(Optional)

| | |
|---|---|
| Pressure Range | -50~350mmHg |
| Accuracy | ±3mmHg or ±1% of reading |
| PR Range | 25-250bpm |
| PR Accuracy | ±2bpm or ±2% (whichever is greater) |

## CO(Optional)

| | |
|---|---|
| Range | 0.20~20.00L/Min |
| Accuracy | ±5% |

## EtCO2 (Optional)

| | |
|---|---|
| CO2 Range | 0~20.0vol% |
| CO2 Accuracy | 0~12vol%:±(0.2vol%+2%of reading) 12~20vol%:±(0.2vol%+6%of reading) |
| AwRR Range | 0~150rpm |
| AwRR Accuracy | mainstream:0~150rpm,±1rpm Sidestream:0~69rpm,±1rpm 70~150rpm,Undefined |

# Patent


### SPO2

Patent

Patent No: ZL 2019 1 0907433.8
ZL 2019 2 1510989.5
ZL 2019 2 1596814.0

### RESP

Patent

Patent No: ZL 2014 1 0429201.3
ZL 2014 2 0489133.5
ZL 2021 2 0480587.6

### EtCO2

Patent

Patent No: ZL 2018 1 0713045.1
ZL 2018 1 0713152.4
ZL 2020 2 1177039.8
ZL 2019 2 0722093.7
ZL 2017 2 0804416.8
ZL 2017 2 0293754.X

### ECG

Patent

Patent No: ZL 2015 0484280.2
ZL 2019 1 0064711.8
ZL 2017 1 0691935.2
ZL 2021 2 0480587.6

### Software copyright patent

Patent No: 2017SR076521

### Appearance patent

Patent No: ZL 2015 3 0297516.2

* The data is subject to change without notice. Please refer to the manual for the contraindications and precautions

Address: Building A-1201, Senyang High-tech Park, Yutang Street, Guangming District, Shenzhen, Guangdong, China
Tel: +86 0755-21384132
Email: sales@szwitleaf.com
Web: www.szwitleaf.com

CE 0123

Witleaf