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:* 吴翔
	POSITION: (MANAGEMENT REPRESENTATIVE)

Digitally signed by Jighili Tatiana
Date: 2023.08.03 16:01:40 MSK
Reason: MoldSign Signature
Location: Moldova