EC Declaration of Conformity

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,Shenzhen,PEOPLE'S REPUBLIC OF CHINA

1.MEDICAL DEVICE: Patient Monitor
Model:XH-60A, XH-60B, XH-60C, XH-60D, SPLF-NP, SPLF-SE, SPLF-MC, SPLF-OX, XH-30A,XH-30B,XH-30C,XH-30D, SATP-MC,SATP-SI,SATP-SE,SATP-OX
CLASSIFICATION: CLASS IIb, RULE 10.
2.MEDICAL DEVICE: Rapid Intervention Capnograph
Model:RICAP
CLASSIFICATION: CLASS IIb, RULE 10.
3.MEDICAL DEVice:Fingertip Pulse Oximeter
Model:WIT-S200/WIT-S400
CLASSIFICATION: CLASS IIa, RULE 10
4.MEDICAL DEVICE: Handheld Pulse Oximeter
Model:WIT-S100/WT-S300
CLASSIFICATION: CLASS IIa, 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.01
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, 2021-04-22

SIGNATURE: *NAME:*

POSITION: (MANAGEMENT REPRESENTATIVE)