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

MEDICAL DEVICE: Patient Monitor
Model:XH-60A, XH-60B, XH-60C, XH-60D, SPLF-NP, SPLF-SE, SPLF-MC, SPLF-OX

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

STANDARDS APPLIED: SEE WL-YF-XH60-055, APPLIED STANDARDS LIST.

NOTIFIED BODY: TÜV SÜD Product Service GmbH
Ridlerstraße 65·80339 Munich·Germany

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): G1 005136 0002 Rev.00

VALID UNTIL: 2024-04-14

EC REP
EUROPEAN REPRESENTATIVE: Zug Medical Systems (SAS)
2000 Route Des Lucioles, Les Algorithmes Aristote A, CS 90029, Sophia Antipolis 06901, France

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: SHENZHEN 2019-04-16

SIGNATURE: *NAME:*

POSITION: (MANAGEMENT REPRESENTATIVE)