DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER: Shenzhen MedKe Technology Co., Ltd.
4/F, Bldg.A1, Anle Ind. Zone, Hangcheng RD., Baoan District, 518126 Shenzhen, China

EUROPEAN REPRESENTATIVE:
Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

PRODUCT: SPO2 SENSORS, GMDN : 17594
MODEL:P3119 , P4119, P5119, P6119, P7119, P8119, P9119

CLASSIFICATION: Class IIb, Rule X, Per Annex IX of Directive 93/42/EEC

CONFORMITY ASSESSMENT ROUTE: Annex II excluding 4

WE, THE MANUFACTURER, HEREWITH DECLARE UNDER OUR SOLE RESPONSIBILITY 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 ARE EXCLUSIVELY RESPONSIBLE FOR THIS DOC.

STANDARDS APPLIED:
ISO 80601-2-61:2017, ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, EN60601-1-2:2014, EN 60601-1:2006/A1:2013, ISO15233-1:2016, EN ISO 14971:2012

FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH • CERTIFICATION BODY • RIDLERSTRABE 65•80339 MUNICH•GERMANY

IDENTIFICATION NUMBER: CE 0123

(EC) CERTIFICATE(S): **G1 085432 0004 REV.00**

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Name: Zhuo Chuanyan
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