



## 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*

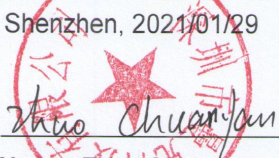
**NOTIFIED BODY:** TÜV SÜD PRODUCT SERVICE GMBH • CERTIFICATION BODY •  
RIDLERSTRABE 65•80339 MUNICH•GERMANY

**IDENTIFICATION NUMBER:**  0123

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

**START OF CE-MARKING:** 2014.1.22

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**SIGNATURE:**   
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