DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	**Sino-Hero(Shenzhen) Bio-Medical Electronics Co., LTD** A area,Second Floor, First Building, Tongkangfu Industrial Park, Yingrenshi Community, Shiyan Sub-District, Bao'an District, 518108,Shenzhen P. R. China
MEDICAL DEVICE:	Pulse Oximeter/ S8
UMDNS CODE	17148
CLASSIFICATION - *ANNEX IX*:	CLASS IIB, RULE 10
CONFORMITY ASSESSMENT ROUTE:	ANNEX II EXCLUDING 4

WE, (**Sino-Hero(Shenzhen) Bio-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.

STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 M NCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	**G1 071165 0013 Rev.02**
EC REP EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING: 2009-11-19

PLACE, DATE OF DECLARATION: *SHENZHEN, 2019-11-04*

SIGNATURE:

BEN LIN
VICE GENERAL MANAGER

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All applicable harmonized Standard as bellows:
IEC 60601-1:2005 + A1: 2012
IEC 60601-1-2:2007
ISO 10993-1:2009
ISO 15223-1:2012
EN ISO 14971:2012
ISO 80601-2-61:2011