

EC DECLARATION OF CONFORMITY MEDICAL DEVICES DIRECTIVE 93/42/EEC

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

PRODUCT: NAME: PULSE OXIMETER PROBES
MODEL: SEE ATTACHED LIST

CLASSIFICATION: *I Ib, Rule 10*

CONFORMITY ASSESSMENT ROUTE: *EC Directive 93/42/EEC annex II excluding section 4*

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE MDD 93/42/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

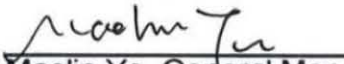
STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTRASSE 65, 80339 MUNICH, GERMANY

NOTIFY BODY NUMBER 0123

(EC) CERTIFICATE(S): *EC CERTIFICATE(S) NUMBER(S): G1 067303 0017 REV. 00*

PLACE, DATE OF ISSUE: *SHENZHEN CITY, 25th May. 2020*

SIGNATURE: 
Maolin Ye, General Manager
NAME, POSITION (RESPONSIBLE SENIOR EXECUTIVE)

**ATTACHMENT 1—LIST OF (HARMONISED - EN) STANDARDS
FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED**

No.	Reference No.	Standard Name
1.	EN 60601-1:2006/A1:2013 IEC 60601-1:2005/A1:2012	Medical electrical equipment – Part 1:General requirements for basic safety and essential performance
2.	EN 60601-1-2:2015 (IEC 60601-1-2:2014)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances- Requirements and tests
3.	EN ISO 80601-2-61:2011 (ISO 80601-2-61:2011)	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
4.	EN1041: 2008	Information supplied by the manufacturer of medical devices
5.	EN ISO 15223-1:2016 (ISO 15223-1:2016)	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
6.	EN ISO 10993-1:2009/AC:2010 (ISO 10993-1:2009)	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
7.	EN ISO 10993-5:2009 (ISO 10993-5:2009)	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
8.	EN ISO 10993-10:2010 (ISO 10993-10:2010)	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
9.	EN ISO 14971:2012 (ISO 14971:2007)	Medical devices – Application of risk management to medical devices

ATTACHMENT 2—MODEL CODE LIST OF PULSE OXIMETER PROBES

Table 1 Reusable Pulse Oximeter Probes

Name of Product: Pulse Oximeter probes (Resuable) Rule of classification: Rule10 Classification: II b Validity of Certificate: G1 067303 0017 Rev.00 GMDN Code: 37808		
Type	Models	Wire type
Adult finger clip SpO ₂ sensor	S0076B-S, S0084B-S, S0044B-S, S0052B-S, S0036B-S, S0014B-S, S0123B-S, S0099B-S, S0018B-S, S0010B-S, S0026B-S, S0005B-S, S0080B-S, S0062B-S, S0020B-S, S0079B-S, S0015B-S,	short wire
	S0153B-S, S0152B-S, S0132B-S, S0143B-S, S0108B-S, S0142B-S	short wire
	S0076B-L, S0084B-L, S0044B-L, S0052B-L, S0036B-L, S0014B-L, S0123B-L, S0099B-L, S0018B-L, S0010B-L, S0026B-L, S0005B-L, S0080B-L, S0062B-L, S0020B-L, S0079B-L, S0015B-L, S0153B-L, S0152B-L, S0132B-L, S0143B-L, S0108B-L, S0142B-L, S0111B-L, S0101B-L, S0029B-L, S0121B-L, S0065B-L, S0071B-L, S0007B-L, S0112B-L, S0063B-L, S0059B-L, S0100B-L, S0127B-L, S0025B-L, S0002B-L, S0122B-L, S0128B-L, S0038B-L, S0061B-L, S0006B-L, S0094B-L, S0083B-L, S0057B-L, S0019B-L, S0102B-L, S0115B-L, S0144B-L, S0103B-L, S0009B-L, S0040B-L, S0016B-L, S0129B-L, S0134B-L, S0013B-L, S0116B-L, S0053B-L, S0011B-L, S0045B-L, S0012B-L, S0117B-L, S0001B-L, S0069B-L, S0109B-L, S0106B-L, S0082B-L, S0091B-L, S0139B-L, S0140B-L, S0003B-L, S0023B-L, S0156B-L, S0028B-L, S0118B-L, S0078B-L, S0072B-L, S0119B-L, S0145B-L, S0120B-L, S0035B-L, S0004B-L, S0089B-L, S0041B-L, S0066B-L, S0064B-L, S0150B-L, S0141B-L, S0058B-L, S0090B-L, S0021B-L, S0113B-L, S0024B-L, S0155B-L, S0160B-L.	Long wire
Pediatric finger clip SpO ₂ sensor	S0076C-S, S0084C-S, S0044C-S, S0052C-S, S0036C-S, S0014C-S, S0123C-S, S0099C-S, S0018C-S, S0010C-S, S0026C-S, S0005C-S, S0080C-S, S0062C-S, S0020C-S, S0079C-S, S0015C-S,	short wire
	S0153C-S, S0152C-S, S0132C-S, S0143C-S, S0108C-S, S0142C-S, S0136C-S	short wire
	S0076C-L, S0084C-L, S0044C-L, S0052C-L, S0036C-L, S0014C-L, S0123C-L, S0099C-L, S0018C-L, S0010C-L, S0026C-L, S0005C-L, S0080C-L, S0062C-L, S0020C-L, S0079C-L, S0015C-L, S0153C-L, S0152C-L, S0132C-L, S0143C-L, S0108C-L, S0142C-L, S0111C-L, S0101C-L, S0029C-L, S0121C-L, S0065C-L, S0071C-L, S0007C-L, S0112C-L, S0063C-L, S0059C-L, S0100C-L, S0127C-L, S0025C-L, S0002C-L, S0122C-L, S0128C-L, S0038C-L, S0061C-L, S0006C-L, S0094C-L, S0083C-L, S0057C-L, S0019C-L, S0102C-L, S0115C-L, S0144C-L, S0103C-L, S0009C-L, S0040C-L, S0016C-L, S0129C-L, S0134C-L, S0013C-L, S0116C-L, S0053C-L, S0011C-L, S0045C-L, S0012C-L, S0117C-L, S0001C-L, S0069C-L, S0109C-L, S0106C-L, S0082C-L, S0091C-L, S0139C-L, S0140C-L, S0003C-L, S0023C-L, S0156C-L, S0028C-L, S0118C-L, S0078C-L, S0072C-L, S0119C-L, S0145C-L, S0120C-L, S0035C-L, S0004C-L, S0089C-L, S0041C-L, S0066C-L, S0064C-L, S0150C-L, S0141C-L, S0058C-L, S0090C-L, S0021C-L, S0113C-L, S0024C-L, S0155C-L, S0160C-L.	Long wire
Adult silicone soft SpO ₂ sensor	S0076D-S, S0084D-S, S0044D-S, S0052D-S, S0036D-S, S0014D-S, S0123D-S, S0099D-S, S0018D-S, S0010D-S, S0026D-S, S0005D-S, S0080D-S, S0062D-S, S0020D-S, S0079D-S, S0015D-S,	short wire
	S0153D-S, S0152D-S, S0132D-S, S0143D-S, S0108D-S, S0142D-S, S0136D-S	short wire

Name of Product: Pulse Oximeter probes (Resuable) Rule of classification: Rule10 Classification: II b Validity of Certificate: G1 067303 0017 Rev.00 GMDN Code: 37808		
Type	Models	Wire type
	S0076D-L, S0084D-L, S0044D-L, S0052D-L, S0036D-L, S0014D-L, S0123D-L, S0099D-L, S0018D-L, S0010D-L, S0026D-L, S0005D-L, S0080D-L, S0062D-L, S0020D-L, S0079D-L, S0015D-L, S0153D-L, S0152D-L, S0132D-L, S0143D-L, S0108D-L, S0142D-L, S0111D-L, S0101D-L, S0029D-L, S0121D-L, S0065D-L, S0071D-L, S0007D-L, S0112D-L, S0063D-L, S0059D-L, S0100D-L, S0127D-L, S0025D-L, S0002D-L, S0122D-L, S0128D-L, S0038D-L, S0061D-L, S0006D-L, S0094D-L, S0083D-L, S0057D-L, S0019D-L, S0102D-L, S0115D-L, S0144D-L, S0103D-L, S0009D-L, S0040D-L, S0016D-L, S0129D-L, S0134D-L, S0013D-L, S0116D-L, S0053D-L, S0011D-L, S0045D-L, S0012D-L, S0117D-L, S0001D-L, S0069D-L, S0109D-L, S0106D-L, S0082D-L, S0091D-L, S0139D-L, S0140D-L, S0003D-L, S0023D-L, S0156D-L, S0028D-L, S0118D-L, S0078D-L, S0072D-L, S0119D-L, S0145D-L, S0120D-L, S0035D-L, S0004D-L, S0089D-L, S0041D-L, S0066D-L, S0064D-L, S0150D-L, S0141D-L, S0058D-L, S0090D-L, S0021D-L, S0113D-L, S0024D-L, S0155D-L, S0160D-L.	Long wire
Pediatric silicone SpO ₂ sensor	S0076P-S, S0084P-S, S0044P-S, S0052P-S, S0036P-S, S0014P-S, S0123P-S, S0099P-S, S0018P-S, S0010P-S, S0026P-S, S0005P-S, S0080P-S, S0062P-S, S0020P-S, S0079P-S, S0015P-S, S0153P-S, S0152P-S, S0132P-S, S0143P-S, S0108P-S, S0142P-S, S0136P-S	short wire
	S0076P-L, S0084P-L, S0044P-L, S0052P-L, S0036P-L, S0014P-L, S0123P-L, S0099P-L, S0018P-L, S0010P-L, S0026P-L, S0005P-L, S0080P-L, S0062P-L, S0020P-L, S0079P-L, S0015P-L, S0153P-L, S0152P-L, S0132P-L, S0143P-L, S0108P-L, S0142P-L, S0111P-L, S0101P-L, S0029P-L, S0121P-L, S0065P-L, S0071P-L, S0007P-L, S0112P-L, S0063P-L, S0059P-L, S0100P-L, S0127P-L, S0025P-L, S0002P-L, S0122P-L, S0128P-L, S0038P-L, S0061P-L, S0006P-L, S0094P-L, S0083P-L, S0057P-L, S0019P-L, S0102P-L, S0115P-L, S0144P-L, S0103P-L, S0009P-L, S0040P-L, S0016P-L, S0129P-L, S0134P-L, S0013P-L, S0116P-L, S0053P-L, S0011P-L, S0045P-L, S0012P-L, S0117P-L, S0001P-L, S0069P-L, S0109P-L, S0106P-L, S0082P-L, S0091P-L, S0139P-L, S0140P-L, S0003P-L, S0023P-L, S0156P-L, S0028P-L, S0118P-L, S0078P-L, S0072P-L, S0119P-L, S0145P-L, S0120P-L, S0035P-L, S0004P-L, S0089P-L, S0041P-L, S0066P-L, S0064P-L, S0150P-L, S0141P-L, S0058P-L, S0090P-L, S0021P-L, S0113P-L, S0024P-L, S0155P-L, S0160P-L.	Long wire
Infant silicone SpO ₂ sensor	S0076E-S, S0084E-S, S0044E-S, S0052E-S, S0036E-S, S0014E-S, S0123E-S, S0099E-S, S0018E-S, S0010E-S, S0026E-S, S0005E-S, S0080E-S, S0062E-S, S0020E-S, S0079E-S, S0015E-S	short wire
	S0153E-S, S0152E-S, S0132E-S, S0143E-S, S0108E-S, S0142E-S	short wire
	S0076E-L, S0084E-L, S0044E-L, S0052E-L, S0036E-L, S0014E-L, S0123E-L, S0099E-L, S0018E-L, S0010E-L, S0026E-L, S0005E-L, S0080E-L, S0062E-L, S0020E-L, S0079E-L, S0015E-L, S0153E-L, S0152E-L, S0132E-L, S0143E-L, S0108E-L, S0142E-L, S0111E-L, S0101E-L, S0029E-L, S0121E-L, S0065E-L, S0071E-L, S0007E-L, S0112E-L, S0063E-L, S0059E-L, S0100E-L, S0127E-L, S0025E-L, S0002E-L, S0122E-L, S0128E-L, S0038E-L, S0061E-L, S0006E-L, S0094E-L, S0083E-L, S0057E-L, S0019E-L, S0102E-L, S0115E-L, S0144E-L, S0103E-L, S0009E-L, S0040E-L, S0016E-L, S0129E-L, S0134E-L, S0013E-L, S0116E-L, S0053E-L, S0011E-L, S0045E-L, S0012E-L, S0117E-L, S0001E-L, S0069E-L, S0109E-L, S0106E-L, S0082E-L, S0091E-L, S0139E-L, S0140E-L,	Long wire

Name of Product: Pulse Oximeter probes (Resuable) Rule of classification: Rule10 Classification: II b Validity of Certificate: G1 067303 0017 Rev.00 GMDN Code: 37808		
Type	Models	Wire type
	S0003E-L, S0023E-L, S0156E-L, S0028E-L, S0118E-L, S0078E-L, S0072E-L, S0119E-L, S0145E-L, S0120E-L, S0035E-L, S0004E-L, S0089E-L, S0041E-L, S0066E-L, S0064E-L, S0150E-L, S0141E-L, S0058E-L, S0090E-L, S0021E-L, S0113E-L, S0024E-L, S0155E-L, S0160E-L.	
Neonate wrap SpO ₂ sensor	S0076F-S, S0084F-S, S0044F-S, S0052F-S, S0036F-S, S0014F-S, S0123F-S, S0099F-S, S0018F-S, S0010F-S, S0026F-S, S0005F-S, S0080F-S, S0062F-S, S0020F-S, S0079F-S, S0015F-S	short wire
	S0153F-S, S0152F-S, S0132F-S, S0143F-S, S0108F-S, S0142F-S	short wire
	S0076F-L, S0084F-L, S0044F-L, S0052F-L, S0036F-L, S0014F-L, S0123F-L, S0099F-L, S0018F-L, S0010F-L, S0026F-L, S0005F-L, S0080F-L, S0062F-L, S0020F-L, S0079F-L, S0015F-L, S0153F-L, S0152F-L, S0132F-L, S0143F-L, S0108F-L, S0142F-L, S0111F-L, S0101F-L, S0029F-L, S0121F-L, S0065F-L, S0071F-L, S0007F-L, S0112F-L, S0063F-L, S0059F-L, S0100F-L, S0127F-L, S0025F-L, S0002F-L, S0122F-L, S0128F-L, S0038F-L, S0061F-L, S0006F-L, S0094F-L, S0083F-L, S0057F-L, S0019F-L, S0102F-L, S0115F-L, S0144F-L, S0103F-L, S0009F-L, S0040F-L, S0016F-L, S0129F-L, S0134F-L, S0013F-L, S0116F-L, S0053F-L, S0011F-L, S0045F-L, S0012F-L, S0117F-L, S0001F-L, S0069F-L, S0109F-L, S0106F-L, S0082F-L, S0091F-L, S0139F-L, S0140F-L, S0003F-L, S0023F-L, S0156F-L, S0028F-L, S0118F-L, S0078F-L, S0072F-L, S0119F-L, S0145F-L, S0120F-L, S0035F-L, S0004F-L, S0089F-L, S0041F-L, S0066F-L, S0064F-L, S0150F-L, S0141F-L, S0058F-L, S0090F-L, S0021F-L, S0113F-L, S0024F-L, S0155F-L, S0160F-L.	Long wire
Adult ear clip SpO ₂ sensor	S0076G-S, S0084G-S, S0044G-S, S0052G-S, S0036G-S, S0014G-S, S0123G-S, S0099G-S, S0018G-S, S0010G-S, S0026G-S, S0005G-S, S0080G-S, S0062G-S, S0020G-S, S0079G-S, S0015G-S	short wire
	S0153G-S, S0152G-S, S0132G-S, S0143G-S, S0108G-S, S0142G-S	short wire
	S0076G-L, S0084G-L, S0044G-L, S0052G-L, S0036G-L, S0014G-L, S0123G-L, S0099G-L, S0018G-L, S0010G-L, S0026G-L, S0005G-L, S0080G-L, S0062G-L, S0020G-L, S0079G-L, S0015G-L, S0153G-L, S0152G-L, S0132G-L, S0143G-L, S0108G-L, S0142G-L, S0111G-L, S0101G-L, S0029G-L, S0121G-L, S0065G-L, S0071G-L, S0007G-L, S0112G-L, S0063G-L, S0059G-L, S0100G-L, S0127G-L, S0025G-L, S0002G-L, S0122G-L, S0128G-L, S0038G-L, S0061G-L, S0006G-L, S0094G-L, S0083G-L, S0057G-L, S0019G-L, S0102G-L, S0115G-L, S0144G-L, S0103G-L, S0009G-L, S0040G-L, S0016G-L, S0129G-L, S0134G-L, S0013G-L, S0116G-L, S0053G-L, S0011G-L, S0045G-L, S0012G-L, S0117G-L, S0001G-L, S0069G-L, S0109G-L, S0106G-L, S0082G-L, S0091G-L, S0139G-L, S0140G-L, S0003G-L, S0023G-L, S0156G-L, S0028G-L, S0118G-L, S0078G-L, S0072G-L, S0119G-L, S0145G-L, S0120G-L, S0035G-L, S0004G-L, S0089G-L, S0041G-L, S0066G-L, S0064G-L, S0150G-L, S0141G-L, S0058G-L, S0090G-L, S0021G-L, S0113G-L, S0024G-L, S0155G-L, S0160G-L.	Long wire
Forehead SpO ₂ sensor and Neonate wrap sensor	S0076I-S, S0084I-S, S0044I-S, S0052I-S, S0036I-S, S0014I-S, S0123I-S, S0099I-S, S0018I-S, S0010I-S, S0026I-S, S0005I-S, S0080I-S, S0062I-S, S0020I-S, S0079I-S, S0015I-S	short wire
	S0153I-S, S0152I-S, S0132I-S, S0143I-S, S0108I-S, S0142I-S	short wire

Name of Product: Pulse Oximeter probes (Resuable) Rule of classification: Rule10 Classification: II b Validity of Certificate: G1 067303 0017 Rev.00 GMDN Code: 37808		
Type	Models	Wire type
	S0076I-L, S0084I-L, S0044I-L, S0052I-L, S0036I-L, S0014I-L, S0123I-L, S0099I-L, S0018I-L, S0010I-L, S0026I-L, S0005I-L, S0080I-L, S0062I-L, S0020I-L, S0079I-L, S0015I-L, S0153I-L, S0152I-L, S0132I-L, S0143I-L, S0108I-L, S0142I-L, S0111I-L, S0101I-L, S0029I-L, S0121I-L, S0065I-L, S0071I-L, S0007I-L, S0112I-L, S0063I-L, S0059I-L, S0100I-L, S0127I-L, S0025I-L, S0002I-L, S0122I-L, S0128I-L, S0038I-L, S0061I-L, S0006I-L, S0094I-L, S0083I-L, S0057I-L, S0019I-L, S0102I-L, S0115I-L, S0144I-L, S0103I-L, S0009I-L, S0040I-L, S0016I-L, S0129I-L, S0134I-L, S0013I-L, S0116I-L, S0053I-L, S0011I-L, S0045I-L, S0012I-L, S0117I-L, S0001I-L, S0069I-L, S0109I-L, S0106I-L, S0082I-L, S0091I-L, S0139I-L, S0140I-L, S0003I-L, S0023I-L, S0156I-L, S0028I-L, S0118I-L, S0078I-L, S0072I-L, S0119I-L, S0145I-L, S0120I-L, S0035I-L, S0004I-L, S0089I-L, S0041I-L, S0066I-L, S0064I-L, S0150I-L, S0141I-L, S0058I-L, S0090I-L, S0021I-L, S0113I-L, S0024I-L, S0155I-L, S0160I-L.	Long wire

Table 2 Disposable Pulse Oximeter Probes

Name of Product: Pulse Oximeter probes (Disposable) Rule of classification: Rule10		Classification: II b Validity of Certificate: G1 067303 0017 Rev.00 GMDN Code: 31658
Type	Models	Wire type
Adult Disposable SpO ₂ sensor	S0076J-S, S0044J-S, S0036J-S, S0014J-S, S0123J-S, S0099J-S, S0020J-S, S0010J-S, S0026J-S, S0069J-S, S0005J-S, S0080J-S, S0062J-S, S0079J-S, S0136J-S, S0015J-S, S0153J-S	Short wire
	S0136 J-L	Long wire
Pediatric Disposable SpO ₂ sensor	S0076K-S, S0044K-S, S0036K-S, S0014K-S, S0123K-S, S0099K-S, S0020K-S, S0010K-S, S0026K-S, S0069K-S, S0005K-S, S0080K-S, S0062K-S, S0079K-S, S0136K-S, S0015K-S, S0153K-S	Short wire
	S0136K-L	Long wire
Infant Disposable SpO ₂ sensor	S0076L-L, S0044L-L, S0036L-L, S0014L-L, S0123L-L, S0099L-L, S0020L-L, S0010L-L, S0026L-L, S0069L-L, S0005L-L, S0080L-L, S0062L-L, S0079L-L, S0136L-L, S0015 L-L, S0153 L-L,	Long wire
	S0015L-S	Short wire
Neonatal/Adult Disposable sensor	S0076M-L, S0044M-L, S0036M-L, S0014M-L, S0123M-L, S0099M-L, S0020M-L, S0010M-L, S0026M-L, S0069M-L, S0005M-L, S0080M-L, S0062M-L, S0079M-L, S0136M-L, S0015 M-L S0153M-L,	Long wire
	S0015 M-S	Short wire
Comfort(Non-adhesive) Disposable SpO ₂	S0010N-L, S0026N-L, S0136N-L, S0015 N-L, S0153N-L,	Long wire
	S0015N-S	Short wire