

DECLARATION OF CONFORMITY

Manufacturer: Shenzhen Sonka Medical Technology CO.,Limited

Address: Floor 6, Block 8, Zhongyuntai Technology Industrial Park, Songbai Road, Shiyan Street, Baoan District, Shenzhen, Guangdong, China

Product Names: Clinical weighing Scale , **Model:** SK-T8, SK-E600A , SK-X9L , SK-X90 , SK-X60 , SK-X60HD , SK-L08

Trade name: SONKA

This product conforms to the following standards:

No.	Standard Number	Standard Title	Remark
1	EN ISO 15223-1:2016	Medical device – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements (ISO15223-1:2016)	
2	EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices -Part 1: Evaluation and testing within a riskmanagement process (ISO 10993-1:2009)	
3	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO10993-5:2009)	
4	EN ISO 10993-10:2010	Biological evaluation of medical devices –Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	
5	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes	
6	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971: 2007, Corrected version 2007-10-01)	
7	IEC 60601-1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2012) Edition 3	
8	EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility -Requirements and tests EN 60601-1-2:2015 (Modified)	
9	EN 60601-1-6:2010	Medical electrical equipment – Part1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (IEC 60601-1-6:2010)	
10	EN 62304:2006+A1:2015	Medical device software - Software lifecycle Processes IEC 62304:2006	
11	EN ISO 2234-2002	Packaging - Complete, filled transport packages and unit loads - Stacking tests using a static load (ISO 2234:2000)	
12	ISO 2248-1985	Packaging — Complete, filled transport packages — Vertical impact test by dropping	
13	EN ISO 780-2015	Packing-Discription packing- Graphical symbols for handling and storage of packages	
14	EN1060-3: 1997+ A2: 2009	Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems	
15	IEC80601-2-30:	Medical electrical equipment — Part 2-30: Particular	

	2009+ A2: 2013	requirements for basic safety and essential performance of automated non-invasive sphygmomanometers	
16	BS EN ISO 80601-2-61-2011	Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	
17	ISO 80601-2-56:2017+A.1:2018	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	