

Technical File

Aneroid Sphygmomanometer

Drafted by: Zhang Xianchun
Approved by: Wang Yunliang
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WENZHOU BOKANG INSTRUMENTS CO.,LTD Technical File	Version: E/0
	Chapter:
File Modification Record	Pages: 1/1

File Modification Record

NO	Edition NO	Issue Date	Modification content	Recorder
A	BK/TF005-2007	2007.7.20	_____	Zhang Xianchun
B	BK/TF005-2008	2008.1.25	Content is not canonical. Add function and performance description.	Zhang Xianchun
C	BK/TF005-2010	2010.3.15		Zhang Xianchun

D	BK/TF005-2012	2012.4.25		Zhang Xianchun
E	BK/TF005-2014	2014.3.15		Zhang Xianchun

WENZHOU BOKANG INSTRUMENTS CO.,LTD Technical File	Version: E/0
	Chapter: 00
Table of contents	Pages:1/1

Table of contents

1. Manufacturer Information
2. MDD Agreement
3. EC Declaration of Conformity
4. Certificate of ISO 9001/2, ISO 13485, MDD 93/42/EEC approval
5. Product Description (including Product group/planned variations)
6. Classification (According MDD 93/42/EEC Annex IX)
7. Technical Documents (drawings, production plans, component lists, labelling, User manual/ Instruction for Use, 9. Sterile condition and method used, packaging material evaluation, production environmental control program, biocompatibility evaluation)
8. Quality Control
9. Product Life-span
10. Test Reports (testing laboratories, reports)
11. Essential Requirements (MDD 93/42/EEC Annex I)
12. Risk Analysis
13. Applicable standards
14. Labeling and packaging

- 15. Instruction manual
- 16. Clinical Investigation
- 17. Vigilance System
- Attachment 1

WENZHOU BOKANG INSTRUMENTS CO.,LTD	Version: E/0
Technical File	Chapter: 01
Manufacturer Information	Pages:1/1

1. Name and address of manufacturer

Manufacturer: Wenzhou Bokang Instrument Co.,Ltd

Address:No.1500 Haining Road Haibin, Longwan, 325024 Wenzhou, China

Tel: +86-577-86876969 Fax: +86-577-86880123

E-mail: bokang@bokang.com

2,. Name and Address of EU representative

EU representative: Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

Tel: 0049-40-2513175 Fax: 0049-40-255726

E-mail: shholding@hotmail.com

WENZHOU BOKANG INSTRUMENTS CO.,LTD	Version: E/0
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Technical File	Chapter: 02
MDD agreement	Pages:1/1

MDD agreement can be seen in the file:MDD agreement(M/A2013)

WENZHOUBOKANG INSTRUMENTS CO.,LTD	Version: E/0
Technical File	Chapter: 03
declaration of conformity	Pages:1/1

See Attached BK-DC-03/D

WENZHOU BOKANG INSTRUMENTS CO.,LTD Technical File	Version: E/0
Certificate of ISO 9001, ISO 13485, 93/42/EEC MDD approval	Chapter: 04 Pages:1/1

Certificates Number:

ISO 9001: SY 60084255 0001

ISO 13485: SX 60084254 0001

MDD 93/42 EEC: DD 60084253 0001

WENZHOU BOKANG INSTRUMENTS CO.,LTD	Version:E/0
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Technical File	Chapter: 05
Product General Description	Pages:1/4

1. Product Name: Aneroid sphygmomanometer
2. Type name: BK2001,BK2002, BK2004,BK2005,BK2006
BK2007,BK2008, BK2099,BK2010,BK2011,
BK2012,BK2013,BK2015,BK2066
3. Expect purpose: It's used to measure body blood prssure and pluse rate at home or hostipal.
stethoscope should be used together with when measure.

4.1 4、Structural materials and properties

4.1 Composition of product components

It's composed of gauge,cuff with bladder, bulb with both valves

4.2 Main parts and suppliers

No.	parts	specification	supplier
1	gauge case	zinc alloy	Yongzhongxingwang zinc processing plant
3	cuff	nylon/cotton	Longwan Haibin Xiaoxiao processing plant
4	bladder,bulb	latex/pvc	Danyang zhenxing CO., LTD
5	valves	copper	Sun Shi pu processing plant

4.3 Description of Function:

It needs to be used together with stethoscope, mainly for measuring human blood pressure

4.4 technical parameters:

- 1) Accuracy: ± 3 mmHg.
- 2) Unit of measuring: mmHg
- 3) Sub-division: 2mmHg
- 4) Measure scope: 0-300mmHg
- 5) The "0" bit allows error: ± 1 mmHg
- 6) cuff circle: 22-32cm

5、Picture: see attachment 1

6. Main Components:

See attached components list (BK/QR-09-07-2002)

WENZHOU BOKANG INSTRUMENTS CO.,LTD	Version: E/0
Technical File	Chapter: 06
Classification	Pages:1/1

Product: Class I

Classification according to rule 1 of section II of Annex IX, MDD 93/42/EEC

WENZHOU BOKANG INSTRUMENTS CO.,LTD Technical File	Version: E/0
	Chapter:07
Technical Documents	Pages:1/1

1. Drawings, Diagrams:
Picture and chart: see file BK2002-TM。
2. Component list: See Attached BK/QR-09-07-2002
3. Labelling and packaging: See Attached BK-LP-01
- 4: Instruction Manual: See Instruction manual BK-IM-01
5. production procedure; file no. :BK/SC-02
6. inspection procedure; file no. :BK/JY-02
7. production flow chart; file no. :BK-LC-2002

WENZHOU BOKANG INSTRUMENTS CO.,LTD Technical File	Version: E/0
	Chapter:08
Quality Control	Pages:1/1

(1) 生产流程图见BK-LC-2002

(2) environment control

Production environment of this product is not need to reach asepsis requirement. But, it should be a clear, non-pollution environment.

(3) Stock inspection and test

i. Aim: raw material and assist material

ii. Inspection frequency: each batch of material

(4) Before leaving factory inspection (final inspection)

i. Aim: date discrepancy, airproof, zero position, case, cuff, air valve, charge bulb.

ii. Inspection time: finished products before leaving factory

iii. Inspection items: see “ batch test and deliver test report”

(5) Period inspection (model inspection)

i. Aim: date discrepancy, airproof, zero position, case, cuff, air valve, charge bulb

ii. Inspection time:

a) Each year

b) when production procedure is changed a lot.

c) When customer required

iii. test items: see “ model test report”

WENZHOU BOKANG INSTRUMENTS CO.,LTD Technical File	Version: E/0
	Chapter:09
Product Life-span	Pages:1/1

Product Life-span is three years.

WENZHOU BOKANG INSTRUMENTS CO.,LTD	Version: E/0
Technical File	Chapter:10
Test report	Pages:1/1

performance test report:

性能检测报告 : G2003172

ISO 10993-10test report No. : G2004204,G2004203

ISO 10993-5test report No. : G2004204,G2004203

ROSH:

WENZHOU BOKANG INSTRUMENTS CO.,LTD	Version: E/0
Technical File	Chapter:11
Essential Requirement checklist	Pages:1/1

See Report No. BK-ER-02

WENZHOU BOKANG INSTRUMENTS CO.,LTD	Version: E/0
Technical File	Chapter:12
Risk Management	Pages:1/1

See attached. Report No. BK-RA-01

WENZHOU BOKANG INSTRUMENTS CO.,LTD	Version: E/0
Technical File	Chapter:13
Applicable standards	Pages:1/1

EN ISO 14971:2012 Medical devices—Application of risk management to medical devices

DIN EN980-2008 symbols for use in the labeling of medical devices

EN 1041:2008 Information supplied by the manufacturer of medical devices

EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type

ISO 10993-10:2010 biological evaluation of medical devices—
 part 10: Tests for irritation and skin sensitization
 ISO 10993-5:2009 biological evaluation of medical devices-- part 5: Tests for in vitro cytotoxicity
 ISO9001 quality management system requirement

WENZHOU BOKANG INSTRUMENTS CO.,LTD Technical File	Version: E/0
	Chapter:14
Labeling and packaging	Pages:1/1

1. 包装材料要求如下说明：

包装方法	包装材料
小包装	①每只血压表为一小包装 ②用瓦楞套盒包装
大包装	①血压表每50个小包装为一大包装 ③采用五层瓦楞纸箱包装

2、内盒和标签内容见附件：BK-LP-01

Technical File	Chapter:15
Instruction Manual	Pages:1/1

See Instruction manual BK-IM-01

WENZHOU BOKANG INSTRUMENTS CO.,LTD	Version: E/0
Technical File	Chapter:16
Clinical Investigation	Pages:1/1

See clinical evaluation report

BK2013005

Jan 20th, 2003 Hangzhou Red Cross Hospital

WENZHOU BOKANG INSTRUMENTS CO.,LTD Technical File	Version: E/0
	Chapter:17
Vigilance System	Pages:1/1

See procedure file No : BK/QP-23
BK/QP-22