

# Statement of Compliance

This is to state that Technical Documentation (CE/BA001-2012, Rev C) for Product(s)

**Disposable ostomy bag, disposable urostomy bag, disposable colostomy bag,  
disposable ileostomy bag**

(Class I not sterile or measuring via Annex IX Rule I)

Manufactured by

**BAO-Health Medical Instrument Co., Ltd.**

**2<sup>nd</sup> Floor of 8-2 Building, Gaoqiao Industrial Zone, Tongxiang City,  
Zhejiang Province, 314515, P.R. China**

*Has been assessed as meeting the Essential Requirements and relevant  
provisions of EC Directive 93/42/EEC Annex I as amended by 2007/47/EC for  
Medical Devices*

For SGS-CSTC Standards Technical Services Co., Ltd.  
System & Services Certification Division

Reference No: CN/HGH5631

Valid from September 2015 to September 2020  
Issue 1. Certificate since September 2015



**SGS-CSTC Standards Technical  
Services Co., Ltd. Shanghai  
Branch**

SGS Bldg, 11/F, Building B, No. 900,  
Yishan Road, Xuhui District, Shanghai,  
China

While all due care and skill was exercised in carrying out this assessment, SGS-CSTC accepts responsibility only for proven gross negligence. This certificate relates only to the medical device as described in the technical file reviewed on the date shown. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacture and quality control of the products. This is not a legal document and cannot be used as such. This certificate remains the property of SGS-CSTC Standards Technical Services Co., Ltd. to whom it must be returned on request.





# Certificate Of FDA Registration

2018

This is certified that:  
At The Address Stated Below Has Completed U.S. FOOD AND DRUG  
ADMINISTRATION Medical Device Registration Through MTG.

## **BAO-HEALTH MEDICAL INSTRUMENT CO., LTD.**

2nd floor of a8 building, gaoqiao industrial zone,  
tongxiang zhejiang, CHINA 314515

**Owner/Operator Number:10047897**  
**Registration Number:3011495142**

The FDA annual establishment registration fee must be paid between Oct. 1 and Dec. 31 of every year.



*Jacky M. Chuang*

Executive Director

Date: 11-28-2017

**MTG STANDARDS TESTING & CERTIFICATION CENTER** [www.fda.cn.org](http://www.fda.cn.org)

This registration affirms that the above listed company has registered with U.S. Food and Drug Administration pursuant to section 562 of the United States Public Health and  
Antismoke Administration and -express Act of 1994. We are not to be held liable, and makes no other representation or warranty. We do not certify, make any representation  
that is not made to any person or entity other than the named registrant holder. For which the benefit is reserved. MTG, LLC. Inc. assumes no liability to any person or entity, in connec-  
tion with the foregoing. MTG is a private registration agent not affiliated with the U.S. Food and Drug Administration.



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**中华人民共和国**  
**PEOPLE'S REPUBLIC OF CHINA**  
**医疗器械产品出口销售证明**  
**CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS**

证书编号: 浙嘉食药监械出 20180245 号  
 Certificate NO.: 浙嘉食药监械出 20180245 号

产品名称: 造口袋  
 Product (s): Ostomy bag

规格型号: 一件式肠造口袋、一件式尿路造口袋、二件式肠造口袋、二件式尿路造口袋、二件式底盘 (具体规格型号详见附件)

Model: One-piece col/ileostomy bag, One-piece urostomy bag, Two-piece col/ileostomy bag, Two-piece urostomy bag, Skin barrier (See attached for the attachment)

产品注册或备案凭证号: 浙械注准 20172661287  
 Registration certificate (s): 浙械注准 20172661287

生产企业: 桐乡市宝禾医疗器械有限公司  
 Manufacturer: BAO-Health Medical Instrument Co., Ltd.

生产企业住所: 浙江省桐乡市高桥工业区 8-2 幢 2 楼  
 Address of manufacturer: 2nd floor of 8-2 Building, Gaoqiao Industrial Zone, Tongxiang, Zhejiang, P.R.China

生产许可或备案凭证号: 浙食药监械生产许 20180004 号  
 Manufacturing License (s): 浙食药监械生产许 20180004 号

兹证明上述产品已准许在中国生产和销售。该产品出口不受限制, 出口医疗器械的企业应当保证其出口的医疗器械符合进口国 (地区) 的要求。

This is to certify that the above products have been registered to be manufactured and sold in China. The exportation of the product (s) is not restricted. The exporter should assure that exporting medical devices meeting requirements of the importing country (region).

证明有效日期至: 2020 年 07 月 19 日  
 This certification valid until: 2020/07/19

备注:  
 Remark:

Zhejiang Food and Drug Administration  
 (浙江省食品药品监督管理局)



# 附件 ATTACHMENT

证书编号: 浙嘉食药监械出 20180245 号

( 共 5 页 第 1 页 )

Certificate No.: 浙嘉食药监械出 20180245 号

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One-piece col/ileostomy bag							
Series one:							
101TPF	101TP	101TNF	101TN	101SPF	101SP	101SNF	101SN
101BPF	101BP	101BNF	101BN	1011TPF	1011TP	1011TNF	1011TN
1011SPF	1011SP	1011SNF	1011SN	1011BPF	1011BP	1011BNF	1011BN
1012TPF	1012TP	1012TNF	1012TN	1012SPF	1012SP	1012SNF	1012SN
1012BPF	1012BP	1012BNF	1012BN	1013TPF	1013TP	1013TNF	1013TN
1013SPF	1013SP	1013SNF	1013SN	1013BPF	1013BP	1013BNF	1013BN
102TPF	102TP	102TNF	102TN	102SPF	102SP	102SNF	102SN
102BPF	102BP	102BNF	102BN	1021TPF	1021TP	1021TNF	1021TN
1021SPF	1021SP	1021SNF	1021SN	1021BPF	1021BP	1021BNF	1021BN
1022TPF	1022TP	1022TNF	1022TN	1022SPF	1022SP	1022SNF	1022SN
1022BPF	1022BP	1022BNF	1022BN	1023TPF	1023TP	1023TNF	1023TN
1023SPF	1023SP	1023SNF	1023SN	1023BPF	1023BP	1023BNF	1023BN
1113TPF	1113TP	1113TNF	1113TN	1113SPF	1113SP	1113SNF	1113SN
1113BPF	1113BP	1113BNF	1113BN	/	/	/	/
Series two:							
101X00	101X00F	101X01	101X01F	101X02	101X02F	101X03	101X03F
101X04	101X04F	101X05	101X05F	101X06	101X06F	101X07	101X07F
101X08	101X08F	101X09	101X09F	102X00	102X00F	102X01	102X01F
102X02	102X02F	102X03	102X03F	102X04	102X04F	102X05	102X05F
102X06	102X06F	102X07	102X07F	102X08	102X08F	102X09	102X09F
105X00	105X00F	105X01	105X01F	105X02	105X02F	105X03	105X03F
105X04	105X04F	105X05	105X05F	105X06	105X06F	105X07	105X07F
105X08	105X08F	105X09	105X09F	106X00	106X00F	106X01	106X01F
106X02	106X02F	106X03	106X03F	106X04	106X04F	106X05	106X05F
106X06	106X06F	106X07	106X07F	106X08	106X08F	106X09	106X09F
107X00	107X00F	107X01	107X01F	107X02	107X02F	107X03	107X03F
107X04	107X04F	107X05	107X05F	107X06	107X06F	107X07	107X07F
107X08	107X08F	107X09	107X09F	108X00	108X00F	108X01	108X01F
108X02	108X02F	108X03	108X03F	108X04	108X04F	108X05	108X05F
108X06	108X06F	108X07	108X07F	108X08	108X08F	108X09	108X09F
109X00	109X00F	109X01	109X01F	109X02	109X02F	109X03	109X03F
109X04	109X04F	109X05	109X05F	109X06	109X06F	109X07	109X07F
109X08	109X08F	109X09	109X09F	110X00	110X00F	110X01	110X01F
110X02	110X02F	110X03	110X03F	110X04	110X04F	110X05	110X05F
110X06	110X06F	110X07	110X07F	110X08	110X08F	110X09	110X09F
111X00	111X00F	111X01	111X01F	111X02	111X02F	111X03	111X03F
111X04	111X04F	111X05	111X05F	111X06	111X06F	111X07	111X07F
111X08	111X08F	111X09	111X09F	112X00	112X00F	112X01	112X01F

112X02	112X02F	112X03	112X03F	112X04	112X04F	112X05	112X05F
112X06	112X06F	112X07	112X07F	112X08	112X08F	112X09	112X09F
114X00	114X00F	114X01	114X01F	114X02	114X02F	114X03	114X03F
114X04	114X04F	114X05	114X05F	114X06	114X06F	114X07	114X07F
114X08	114X08F	114X09	114X09F	115X00	115X00F	115X01	115X01F
115X02	115X02F	115X03	115X03F	115X04	115X04F	115X05	115X05F
115X06	115X06F	115X07	115X07F	115X08	115X08F	115X09	115X09F
116X00	116X00F	116X01	116X01F	116X02	116X02F	116X03	116X03F
116X04	116X04F	116X05	116X05F	116X06	116X06F	116X07	116X07F
116X08	116X08F	116X09	116X09F	117X00	117X00F	117X01	117X01F
117X02	117X02F	117X03	117X03F	117X04	117X04F	117X05	117X05F
117X06	117X06F	117X07	117X07F	117X08	117X08F	117X09	117X09F
118X00	118X00F	118X01	118X01F	118X02	118X02F	118X03	118X03F
118X04	118X04F	118X05	118X05F	118X06	118X06F	118X07	118X07F
118X08	118X08F	118X09	118X09F	119X00	119X00F	119X01	119X01F
119X02	119X02F	119X03	119X03F	119X04	119X04F	119X05	119X05F
119X06	119X06F	119X07	119X07F	119X08	119X08F	119X09	119X09F
120X00	120X00F	120X01	120X01F	120X02	120X02F	120X03	120X03F
120X04	120X04F	120X05	120X05F	120X06	120X06F	120X07	120X07F
120X08	120X08F	120X09	120X09F	101X00FC	101X01FC	101X02FC	101X03FC
101X04FC	101X05FC	101X06FC	101X07FC	101X08FC	101X09FC	102X00FC	102X01FC
102X02FC	102X03FC	102X04FC	102X05FC	102X06FC	102X07FC	102X08FC	102X09FC
105X00FC	105X01FC	105X02FC	105X03FC	105X04FC	105X05FC	105X06FC	105X07FC
105X08FC	105X09FC	106X00FC	106X01FC	106X02FC	106X03FC	106X04FC	106X05FC
106X06FC	106X07FC	106X08FC	106X09FC	107X00FC	107X01FC	107X02FC	107X03FC
107X04FC	107X05FC	107X06FC	107X07FC	107X08FC	107X09FC	108X00FC	108X01FC
108X02FC	108X03FC	108X04FC	108X05FC	108X06FC	108X07FC	108X08FC	108X09FC
109X00FC	109X01FC	109X02FC	109X03FC	109X04FC	109X05FC	109X06FC	109X07FC
109X08FC	109X09FC	110X00FC	110X01FC	110X02FC	110X03FC	110X04FC	110X05FC
110X06FC	110X07FC	110X08FC	110X09FC	111X00FC	111X01FC	111X02FC	111X03FC
111X04FC	111X05FC	111X06FC	111X07FC	111X08FC	111X09FC	112X00FC	112X01FC
112X02FC	112X03FC	112X04FC	112X05FC	112X06FC	112X07FC	112X08FC	112X09FC
114X00FC	114X01FC	114X02FC	114X03FC	114X04FC	114X05FC	114X06FC	114X07FC
114X08FC	114X09FC	115X00FC	115X01FC	115X02FC	115X03FC	115X04FC	115X05FC
115X06FC	115X07FC	115X08FC	115X09FC	116X00FC	116X01FC	116X02FC	116X03FC
116X04FC	116X05FC	116X06FC	116X07FC	116X08FC	116X09FC	117X00FC	117X01FC
117X02FC	117X03FC	117X04FC	117X05FC	117X06FC	117X07FC	117X08FC	117X09FC
118X00FC	118X01FC	118X02FC	118X03FC	118X04FC	118X05FC	118X06FC	118X07FC
118X08FC	118X09FC	119X00FC	119X01FC	119X02FC	119X03FC	119X04FC	119X05FC
119X06FC	119X07FC	119X08FC	119X09FC	120X00FC	120X01FC	120X02FC	120X03FC
120X04FC	120X05FC	120X06FC	120X07FC	120X08FC	120X09FC	101X00FY	101X01FY
101X02FY	101X03FY	101X04FY	101X05FY	101X06FY	101X07FY	101X08FY	101X09FY
102X00FY	102X01FY	102X02FY	102X03FY	102X04FY	102X05FY	102X06FY	102X07FY
102X08FY	102X09FY	105X00FY	105X01FY	105X02FY	105X03FY	105X04FY	105X05FY
105X06FY	105X07FY	105X08FY	105X09FY	110X00FY	110X01FY	110X02FY	110X03FY
110X04FY	110X05FY	110X06FY	110X07FY	110X08FY	110X09FY	111X00FY	111X01FY

*General*

111X02FY	111X03FY	111X04FY	111X05FY	111X06FY	111X07FY	111X08FY	111X09FY
112X00FY	112X01FY	112X02FY	112X03FY	112X04FY	112X05FY	112X06FY	112X07FY
112X08FY	112X09FY	114X00FY	114X01FY	114X02FY	114X03FY	114X04FY	114X05FY
114X06FY	114X07FY	114X08FY	114X09FY	115X00FY	115X01FY	115X02FY	115X03FY
115X04FY	115X05FY	115X06FY	115X07FY	115X08FY	115X09FY	116X00FY	116X01FY
116X02FY	116X03FY	116X04FY	116X05FY	116X06FY	116X07FY	116X08FY	116X09FY
117X00FY	117X01FY	117X02FY	117X03FY	117X04FY	117X05FY	117X06FY	117X07FY
117X08FY	117X09FY	118X00FY	118X01FY	118X02FY	118X03FY	118X04FY	118X05FY
118X06FY	118X07FY	118X08FY	118X09FY	101X00FYC	101X01FYC	101X02FYC	101X03FYC
101X04FYC	101X05FYC	101X06FYC	101X07FYC	101X08FYC	101X09FYC	102X00FYC	102X01FYC
102X02FYC	102X03FYC	102X04FYC	102X05FYC	102X06FYC	102X07FYC	102X08FYC	102X09FYC
105X00FYC	105X01FYC	105X02FYC	105X03FYC	105X04FYC	105X05FYC	105X06FYC	105X07FYC
105X08FYC	105X09FYC	110X00FYC	110X01FYC	110X02FYC	110X03FYC	110X04FYC	110X05FYC
110X06FYC	110X07FYC	110X08FYC	110X09FYC	111X00FYC	111X01FYC	111X02FYC	111X03FYC
111X04FYC	111X05FYC	111X06FYC	111X07FYC	111X08FYC	111X09FYC	112X00FYC	112X01FYC
112X02FYC	112X03FYC	112X04FYC	112X05FYC	112X06FYC	112X07FYC	112X08FYC	112X09FYC
114X00FYC	114X01FYC	114X02FYC	114X03FYC	114X04FYC	114X05FYC	114X06FYC	114X07FYC
114X08FYC	114X09FYC	115X00FYC	115X01FYC	115X02FYC	115X03FYC	115X04FYC	115X05FYC
115X06FYC	115X07FYC	115X08FYC	115X09FYC	116X00FYC	116X01FYC	116X02FYC	116X03FYC
116X04FYC	116X05FYC	116X06FYC	116X07FYC	116X08FYC	116X09FYC	117X00FYC	117X01FYC
117X02FYC	117X03FYC	117X04FYC	117X05FYC	117X06FYC	117X07FYC	117X08FYC	117X09FYC
118X00FYC	118X01FYC	118X02FYC	118X03FYC	118X04FYC	118X05FYC	118X06FYC	118X07FYC
118X08FYC	118X09FYC	/	/	/	/	/	/

Two-piece col/ileostomy bag

Series one:

2012TPF	2012TP	2012TNF	2012TN	2012SPF	2012SP	2012SNF	2012SN
2012BPF	2012BP	2012BNF	2012BN	2013TPF	2013TP	2013TNF	2013TN
2013SPF	2013SP	2013SNF	2013SN	2013BPF	2013BP	2013BNF	2013BN
2022TPF	2022TP	2022TNF	2022TN	2022SPF	2022SP	2022SNF	2022SN
2022BPF	2022BP	2022BNF	2022BN	2023TPF	2023TP	2023TNF	2023TN
2023SPF	2023SP	2023SNF	2023SN	2023BPF	2023BP	2023BNF	2023BN
2113TPF	2113TP	2113TNF	2113TN	2113SPF	2113SP	2113SNF	2113SN
2113BPF	2113BP	2113BNF	2113BN	/	/	/	/

Series two:

201X00	201X00F	201X01	201X01F	201X02	201X02F	201X03	201X03F
201X04	201X04F	201X05	201X05F	201X06	201X06F	201X07	201X07F
201X08	201X08F	201X09	201X09F	202X00	202X00F	202X01	202X01F
202X02	202X02F	202X03	202X03F	202X04	202X04F	202X05	202X05F
202X06	202X06F	202X07	202X07F	202X08	202X08F	202X09	202X09F
205X00	205X00F	205X01	205X01F	205X02	205X02F	205X03	205X03F
205X04	205X04F	205X05	205X05F	205X06	205X06F	205X07	205X07F
205X08	205X08F	205X09	205X09F	206X00	206X00F	206X01	206X01F
206X02	206X02F	206X03	206X03F	206X04	206X04F	206X05	206X05F
206X06	206X06F	206X07	206X07F	206X08	206X08F	206X09	206X09F

Handwritten signature and a circular stamp with illegible text.

208X00	208X00F	208X01	208X01F	208X02	208X02F	208X03	208X03F
208X04	208X04F	208X05	208X05F	208X06	208X06F	208X07	208X07F
208X08	208X08F	208X09	208X09F	210X00	210X00F	210X01	210X01F
210X02	210X02F	210X03	210X03F	210X04	210X04F	210X05	210X05F
210X06	210X06F	210X07	210X07F	210X08	210X08F	210X09	210X09F
211X00	211X00F	211X01	211X01F	211X02	211X02F	211X03	211X03F
211X04	211X04F	211X05	211X05F	211X06	211X06F	211X07	211X07F
211X08	211X08F	211X09	211X09F	212X00	212X00F	212X01	212X01F
212X02	212X02F	212X03	212X03F	212X04	212X04F	212X05	212X05F
212X06	212X06F	212X07	212X07F	212X08	212X08F	212X09	212X09F
214X00	214X00F	214X01	214X01F	214X02	214X02F	214X03	214X03F
214X04	214X04F	214X05	214X05F	214X06	214X06F	214X07	214X07F
214X08	214X08F	214X09	214X09F	215X00	215X00F	215X01	215X01F
215X02	215X02F	215X03	215X03F	215X04	215X04F	215X05	215X05F
215X06	215X06F	215X07	215X07F	215X08	215X08F	215X09	215X09F
220X00	220X00F	220X01	220X01F	220X02	220X02F	220X03	220X03F
220X04	220X04F	220X05	220X05F	220X06	220X06F	220X07	220X07F
220X08	220X08F	220X09	220X09F	/	/	/	/

Skin barrier

Series one:							
3011	3012	3013	3011Y	3012Y	3013Y	/	/
Series two:							
301X01	302X01	303X01	304X01	305X01	306X01	307X01	308X01
309X01	310X01	311X01	312X01	301X01C	302X01C	303X01C	304X01C
305X01C	306X01C	307X01C	308X01C	309X01C	310X01C	311X01C	312X01C
301X01Y	302X01Y	303X01Y	304X01Y	305X01Y	306X01Y	307X01Y	308X01Y
309X01Y	310X01Y	311X01Y	312X01Y	301X01YC	302X01YC	303X01YC	304X01YC
305X01YC	306X01YC	307X01YC	308X01YC	309X01YC	310X01YC	311X01YC	312X01YC

One-piece urostomy bag

Series one:							
4011TP	4011TN	4012TP	4012TN	4013TP	4013TN	4021TP	4021TN
4022TP	4022TN	4023TP	4023TN	4011TPY	4011TNY	4012TPY	4012TNY
4013TPY	4013TNY	4021TPY	4021TNY	4022TPY	4022TNY	4023TPY	4023TNY
Series two:							
401X01	401X03	401X04	401X06	401X07	401X09	402X01	402X03
402X04	402X06	402X07	402X09	401X01C	401X03C	401X04C	401X06C
401X07C	401X09C	402X01C	402X03C	402X04C	402X06C	402X07C	402X09C
401X01Y	401X03Y	401X04Y	401X06Y	401X07Y	401X09Y	402X01Y	402X03Y
402X04Y	402X06Y	402X07Y	402X09Y	401X01YC	401X03YC	401X04YC	401X06YC
401X07YC	401X09YC	402X01YC	402X03YC	402X04YC	402X06YC	402X07YC	402X09YC



Two-piece urostomy bag

Series one:

4031TP	4031TN	4032TP	4032TN	4033TP	4033TN	4041TP	4041TN
4042TP	4042TN	4043TP	4043TN	/	/	/	/

Series two:

403X01	403X03	403X04	403X06	403X07	403X09	404X01	404X03
404X04	404X06	404X07	404X09	/	/	/	/

Note:

1. "X" in the code could substituted by number 20 to 102, means the maximum size of the plate cutting range 20mm to 102mm. It could be absent, which means no maximum size printed on the plate.
2. "Y" in the code could substituted by number 08-99, means the initial opening size of the plate from 8mm to 99mm, It could be absent, which means the initial opening size is 20mm

(THE END)





# SGS

Certificate CN12/20665

The management system of

## BAO-Health Medical Instrument Co., Ltd.

2<sup>nd</sup> Floor of 8-2 Building, Gaoqiao Industrial Zone,  
Tongxiang City, Zhejiang Province, 314515, P.R. China

has been assessed and certified as meeting the requirements of

### ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Design and manufacture of Single-use Non-sterile Ostomy Bags,  
Single-use Non-sterile Urostomy Bags, Single-use Non-sterile  
Colostomy Bags, Single-use Non-sterile Ileostomy Bags**

This certificate is valid from 1 November 2018 until 31 October 2021  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 11 October 2021

Issue 3. Certified since 31 October 2012

Multiple certificates have been issued for this scope

Authorised by



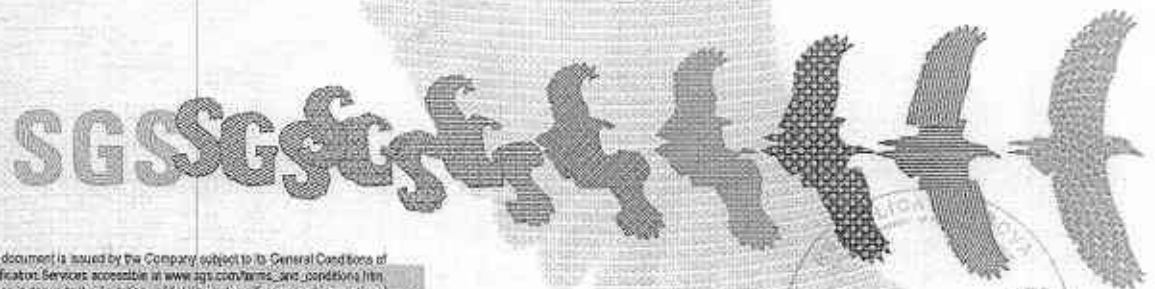
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