EC DECLARATION OF CONFORMITY

MANUFACTURE:	**Jiangsu HanHeng Medical Technology Co., Ltd.** **16-B4, #1 North Qingyang Road, Tianning District, Changzhou, 213017 Jiangsu P.R. China.**
EUROPEAN REPRESENTATIVE:	**Luxus lebenswelt GmbH** **Kochstr.1,47877, Willich, Germany**
MEDICAL DEVICE:	**Disposable Sampling Brushes**
MODLE/TYPE:	**Refer to the Attachment #1**
CLASSIFICATION:	**Class Is, rule 5 of MDD Annex IX**

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED MEDICAL DEVICES MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AND ITS TRANSPOSITIONS IN NATIONAL LAWS WHICH APPLY TO IT. THE DECLARATION IS VALID IN CONNECTION WITH THE "FINAL INSPECTION REPORT" OF THE DEVICE.

CONFORMITY ASSESSMENT PROCEDURE:	**Annex V, MDD 93/42/EEC**
STANDARD APPLIED:	**Refer to the Attachment #2**
NOTIFIED BODY:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2, 90431, Nürnberg, Germany**
NB IDENTIFICATION NUMBER:	**0197**
REGISTRATION NO.:	**DD 60144541 0001**
UMDNS/GMDN Code:	**15018**
EXPIRE DATE OF THE CERTIFICATE:	**2024-05-27**
PLACE, DATE OF ISSUE	**Changzhou, Jiangsu**

SIGNATURE:

Digitally signed by Ceaicovschi Tudor
Date: 2023.02.09 10:35:10 EET
Reason: MoldSign Signature
Location: Moldova

General Manager / Legally Binding Signature

On behalf of Jiangsu HanHeng Medical Technology Co., Ltd

Attachment #1

N0.	Model / Type	N0.	Model / Type	N0.	Model / Type	N0.	Model / Type
1	8101A01	31	8102A04	61	8112A10	91	8120A40
2	8101B01	32	8102B04	62	8112B10	92	8120A50
3	8101A02	33	8102A05	63	8112A11	93	8120A60
4	8101B02	34	8102B05	64	8112B11	94	8121A01
5	8101A03	35	8102A06	65	8112A12	95	8121B01
6	8101B03	36	8102B06	66	8112B12	96	8121A02
7	8101A04	37	8110A10	67	8113A10	97	8121B02
8	8101B04	38	8110B10	68	8113B10	98	8121A03
9	8101A05	39	8110A11	69	8113A11	99	8121B03
10	8101B05	40	8110B11	70	8113B11	100	8121A10
11	8101A06	41	8110A12	71	8113A12	101	8121B10
12	8101B06	42	8110B12	72	8113B12	102	8121A11
13	8101A10	43	8110A40	73	8112A40	103	8121B11
14	8101B10	44	8110B40	74	8112B40	104	8121A12
15	8101A11	45	8110A50	75	8113A40	105	8121B12
16	8101B11	46	8110B50	76	8113B40	106	8130A20
17	8101A12	47	8110A60	77	8112A50	107	8130B20
18	8101B12	48	8110B60	78	8112B50	108	8130A21
19	8101A20	49	8111A10	79	8113A50	109	8130B21
20	8101B20	50	8111B10	80	8113B50		
21	8101A21	51	8111A11	81	8112A60		
22	8101B21	52	8111B11	82	8112B60		
23	8101A30	53	8111A12	83	8113A60		
24	8101B30	54	8111B12	84	8113B60		
25	8102A01	55	8111A40	85	8120A01		
26	8102B01	56	8111B40	86	8120A02		
27	8102A02	57	8111A50	87	8120A03		
28	8102B02	58	8111B50	88	8120A10		
29	8102A03	59	8111A60	89	8120A11		
30	8102B03	60	8111B60	90	8120A12		

Attachment #2

European Norms and Standards and other Documents supporting Technical Files:

1. EN ISO 13485:2016+AC-2018 Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485:2016)
2. EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
3. EN 1041:2008 Information supplied by the manufacturer of medical devices
4. EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019)
5. EN ISO 10993-1:2009+AC-2010 Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process. Technical Corrigendum 1 (ISO 10993-1:2009/Cor 1:2010)
6. EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
7. EN ISO 10993-7:2008+AC-2009 Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals. Technical Corrigendum 1 (ISO 10993-7:2008/Cor 1:2009)
8. EN ISO 10993-10:2013 Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization
9. EN ISO 10993-12:2012 Biological evaluation of medical devices. Part 12: Sample preparation and reference materials
10. ISO 14698-1:2003 Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
11. ISO 14698-2:2003 Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
12. EN 556-1:2001+AC-2006 Sterilization of medical devices. Requirements for medical devices to be designated 'STERILE'. Part 1: Requirements for terminally sterilized medical devices
13. EN ISO 11135:2014+A1-2019 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/Amd 1:2018)
14. EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
15. EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
16. EN ISO 14644-1:2015 Cleanrooms and associated controlled environments. Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
17. EN ISO 14644-2:2015 Cleanrooms and associated controlled environments. Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
18. EN ISO 11737-1:2018 Sterilization of health care products. Microbiological methods. Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
19. ISO 11737-2:2019 Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
20. EN 62366-1:2015+AC-2016 Medical devices - Part 1: Application of usability engineering to medical devices
21. MEDDEV 2.7.1 Rev.4 Clinical evaluation: Guidance under the Directive 93/42 / EEC and 90/385 / EEC manufacturers and notified bodies
22. MDD 93/42/EEC Medical Device Directive
23. EN ISO 11138-1:2017 Sterilization of health care products. Biological indicators. Part 1: General requirements (ISO 11138-1:2017)
24. EN ISO 11138-2:2017 Sterilization of health care products. Biological indicators. Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)

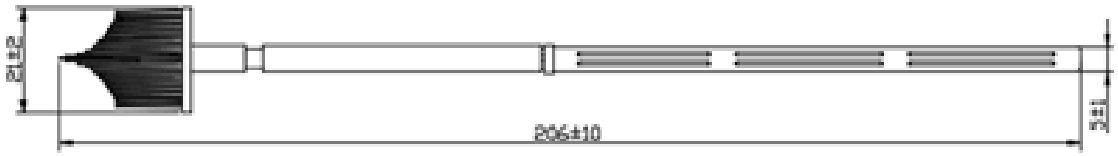
Boen Healthcare Co., Ltd.

Technical date sheet of cervix examination brush

1. Product Description

Disposable cervix examination brush is intended for the gynecological examination. It is composed of brush head and handle. The brush head is made of PE and the handle is made of PP. The brush can be with push tube or without push tube, the push tube is made of PP.

2. Product Construction



Type B

3. Manufacturing Process

Raw material → Injection → Assembly → Packing and Sealing → Sterilization → Resolving → Inspection → Storage

Injection, assembly, packing and sealing is key process, it should be made in one hundred thousand clean room.

Sterilization is a special process.

4. Technical Requirement

Cervix examination brush should be smooth, no burr, no flying edges.

The brush head should be flexible.

The brush head and the handle can be connected firmly.

After being sterilized by EO, the residue should be less than 10mg/kg after 7 days.

5. Packing Details

It is individually packed in blister paper bag, 100pcs/box, 2000pcs/ctn.