BOENMED®

BOEN HEALTHCARE CO., LTD.

DECLARATION

To whom it may concern,

Digitally signed by Ceaicovschi Tudor
Date: 2025.05.15 13:36:45 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

We hereby to declare that Jiangsu Hanheng Medical Technology Co. Ltd. is the factory of Boen Healthcare Co., Ltd. to produce Disposable Sampling Brushes.

Sincerely!

Boen Healthcare Co., Ltd.

Jiangsu Hanheng Medical Technology Co., Ltd.

May. 15, 2025

EU DECLARATION OF CONFORMITY

MANUFACTURE:	Jiangsu HanHeng Medical Technology Co., Ltd. #118 Xinyuan 3rd Road, Xinbei District, Changzhou, 213031 Jiangsu P.R. China
SRN:	CN-MF-000018784
EUROPEAN REPRESENTATIVE:	Luxus lebenswelt GmbH Kochstr.1,47877, Willich, Germany
SRN:	DE-AR-000005110
Product Name:	Disposable Sampling Brushes
MODLE/TYPE:	Refer to the Attachment #1
BASIC UDI-DI:	697369781185RV
EMDN CODE:	A1101
CLASSIFICATION:	Class Is , rule 5 of Regulation (EU) 2017/745 Annex VIII

WE, THE MANUFACTURER, HEREWITH DECLARE UNDER OUR SOLE RESPONSIBILITY THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION (EU) 2017/745 ON MEDICAL DEVICES.

CONFORMITY ASSESSMENT PROCEDURE:	Annex IX, Regulation (EU) 2017/745
APPLIED STANDARD & COMMON SPECIFICATION:	Refer to the Attachment #2
NOTIFIED BODY:	TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany
NB IDENTIFICATION NUMBER:	0197
EU CERTIFICATE NO.:	HZ 2054615-1
EXPIRY DATE OF THE CERTIFICATE:	2030-02-04
PLACE, DATE OF ISSUE	Changzhou, Jiangsu

SIGNATURE:

Xia Yue ming 2025.02.14

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 Medical devices. Quality management systems. Requirements for regulatory purposes
2. MDR 2017/745/EU Medical Device Regulation
3. EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
4. EN ISO 20417-2021 Medical devices - Information to be supplied by the manufacturer
5. EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
6. EN CEN ISO/TR 24971-2020 Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
7. EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8. EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
9. EN ISO 10993-7-2008+A1-2022 Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals
10. EN ISO 10993-10:2013 Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization
11. EN ISO 10993-12:2021 Biological evaluation of medical devices. Part 12: Sample preparation and reference materials
12. EN 17141: 2020 Cleanrooms and associated controlled environments - Biocontamination control
13. 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
14. 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
15. EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
16. EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
17. EN ISO 14644-1:2015 Cleanrooms and associated controlled environments. Part 1: Classification of air cleanliness by particle concentration
18. 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
19. EN ISO 11737-1:2018 Sterilization of health care products. Microbiological methods. Part 1: Determination of a population of microorganisms on products
20. 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
21. EN 62366-1-2015+A1-2020 Medical devices - Part 1: Application of usability engineering to medical devices
22. MEDDEV 2.7.1 Rev.4 Clinical evaluation: Guidance under the Directive 93/42 / EEC and 90/385 / EEC manufacturers and notified bodies
23. EN ISO 11138-1:2017 Sterilization of health care products. Biological indicators. Part 1: General requirements
24. EN ISO 11138-2:2017 Sterilization of health care products. Biological indicators. Part 2: Biological indicators for ethylene oxide sterilization processes

Technical Data Sheet

Pap Smear Brush

Cat.No. 110208-110220

Definition

Pap smear brush, also known as cervical brush or cytobrush, is designed for collecting cells from the cervix during a Pap smear (Papanicolaou smear) procedure, which is used for cervical cancer screening.

Intended Use

The Pap test brush is mainly used for clinical use of the natural channels for biological samples.

Component

1. The disposable sampling brush consists of a sampling head (with or without a ball tip) and a sampling handle.
2. The sampling head is stainless steel 304 wound, and the bristles are made of PA66 nylon wire.
3. The ball tip is made of epoxy material and the sampling handle is made of PP (Polypropylene).

Type A, Without a ball tip

Type B, With a ball tip

Specification

Cat. No.	Description	Qty/Case (Pcs)
110208	Pap Smear Brush, Type A, Plastic Tube Handle, Non Sterile	5000
110209	Pap Smear Brush, Type A, Plastic Tube Handle, Individual Sterile Pack	3000
110210	Pap Smear Brush, Type A, Injection Plastic Handle, Non Sterile	5000
110211	Pap Smear Brush, Type A, Injection Plastic Handle, Individual Sterile Pack	3000
110212	Pap Smear Brush, Type A, Plastic Tube with Anti-slip Handle, Non Sterile	5000

Pap Smear Brush

Cat.No. 110208-110220

110213	Pap Smear Brush, Type A, Plastic Tube with Anti-slip Handle, Individual Sterile Pack	3000
110218	Pap Smear Brush, Type A, Plastic Tube Handle 170mm, Non Sterile	5000
110219	Pap Smear Brush, Type A, Plastic Tube Handle 170mm, Sterile	2000
110220	Pap Smear Brush, Type A, Plastic Tube Handle 145mm, Non Sterile	5000
110214	Pap Smear Brush, Type B, Plastic Tube Handle, Non-sterile	2000
110215	Pap Smear Brush, Type B, Plastic Tube Handle, Individual Sterile Pack	2000
110216	Pap Smear Brush, Type B, Injection Handle, Non-sterile	2000
110217	Pap Smear Brush, Type B, Injection Handle, Individual Sterile Pack	2000

Steps to Use

1. Open the pouch, and take out the Disposable endocervical brush.
2. Insert the sampling head into the sampling site. Apply gentle pressure until the two wing bristles are in close contact with the sampling site.
3. Hold the sampling handle with your thumb and forefinger. Maintaining gentle pressure, after rotating 2～5 Turns in one direction, take out the pap smear test brush for sample testing.

Precaution

1. Please check the pouch package and the pap test brush carefully before use. If either of them is damaged, it is strictly forbidden to use.
2. Please read the instruction manual carefully, and pay attention to the expiry date of the product before use. Do not use it after the deadline.
3. This cytology brush is disposable. The cytobrush for pap smear should be strictly in accordance with the aseptic operation specifications. Please destroy the pap brush immediately after use.
4. The disposal of wastes shall be carried out in accordance with national environmental protection laws and regulations.

Storage and Transportation

1. The cervical smear brush should be stored in a room with a temperature of -10℃～40℃, relative humidity of not more than 80%, good ventilation, and no corrosive gas.
2. The brush for pap smear should be protected from heavy pressure, strong vibration, direct sunlight, high temperature, moisture, rain, and corrosive gases or liquids during transportation.

Sterilization: EO

Shelf Life: 5 years

Definitions of Signs

STERILE EO	**Sterilized using ethylene oxide**		**Do not re-use**

Pap Smear Brush

Cat.No. 110208-110220

	**Do not use if package is damaged**		**Do not resterilize**
	**Caution**		**Fragile, handle with care**
	**Upward**		**Keep dry**
	**Batch code**		**Use-by date**
	**Manufacturer**		**Authorized representative in the European Community**
	**Date of manufacture**		**Consult instructions for use**
	**Temperature limit**		**Keep away from sunlight**
	**Stacking limit by number**		**Medical device**
	**Thrown into the trash after use**		