

宁波新跃医疗科技股份有限公司

使用说明书

产品名称：一次性使用呼吸过滤器

文件编号：RD/S-115-0002

文件版本：A/0

文件更改履历 Change History				
版次 Ver.	修改内容 Change Descriptions	修改人 Author	日期 Date	修改单号 Change No.
A/0	原版	谭茜媛	2020.07.13	/
文件批准栏 Approval Column For Document				
编制 Prepared By	谭茜媛	日期 Date	2020.7.13	
审核 Checked By	董行 薛 2020.7.13	日期 Date	2020.7.13	
批准 Approved By	薛	日期 Date	2020.7.13	

CE Technical File Disposable Heat and Moisture Exchanger Filters	File No: RD/S-115-0002
	Rev. No: A/0

Instruction for Use

1. Product Name:

Disposable Heat and Moisture Exchanger Filters

2. Models and Specifications:

No.	Model	Spec.	No.	Model	Spec.	No.	Model	Spec.
1	A1	3000NS	53	F2	3034NS	105	G2	3058NS
2		3001NS	54		3035NS	106		3158NS
3		3002NS	55		3134NS	107	G3	3308NS
4		3100NS	56		3135NS	108		3309NS
5		3101NS	57		3036NS	109		3310NS
6		3102NS	58		3037NS	110		3311NS
7	B1	3003NS	59	3038NS	111	3312NS		
8		3004NS	60	3039NS	112	3408NS		
9		3005NS	61	3040NS	113	3410NS		
10		3103NS	62	3041NS	114	3411NS		
11		3104NS	63	3042NS	115	3412NS		
12		3105NS	64	3043NS	116	G4	3313NS	
13	B2	3006NS	65	3044NS	117		3314NS	
14		3007NS	66	3045NS	118		3315NS	
15		3106NS	67	3046NS	119		3316NS	
16		3107NS	68	3047NS	120		3317NS	
17	B3	3008NS	69	3048NS	121		3318NS	
18		3009NS	70	3049NS	122	3319NS		
19		3108NS	71	3050NS	123	3320NS		
20		3109NS	72	3051NS	124	H1	3056NS	
21	C1	3016NS	73	3136NS	125		3057NS	
22		3017NS	74	3137NS	126	I1	3321NS	
23	D1	3010NS	75	3138NS	127		3322NS	
24		3011NS	76	3139NS	128		3323NS	
25		3110NS	77	3140NS	129		3324NS	
26		3111NS	78	3141NS	130		3325NS	
27		D2	3012NS	79	3142NS		131	3421NS

CE Technical File Disposable Heat and Moisture Exchanger Filters	File No: RD/S-115-0002
	Rev. No: A/0

28		3013NS	80		3143NS	132		3422NS
29		3112NS	81		3144NS	133		3423NS
30		3113NS	82		3145NS	134		3424NS
31		D3	3014NS		83	3146NS		135
32	3015NS		84	3147NS				
33	3114NS		85	3148NS				
34		3115NS	86	3149NS				
35	E1	3059NS	87	3150NS				
36		3060NS	88	3151NS				
37		3018NS	89	F4	3052NS			
38		3019NS	90		3053NS			
39		3020NS	91		3152NS			
40		3021NS	92		3153NS			
41	F1	3022NS	93	F5	3054NS			
42		3023NS	94		3055NS			
43		3024NS	95		3154NS			
44		3025NS	96		3155NS			
45		3026NS	97	G1	3300NS			
46		3027NS	98		3301NS			
47		3028NS	99		3302NS			
48		3029NS	100		3303NS			
49	3030NS	101	3304NS					
50	3031NS	102	3305NS					
51	3032NS	103	3306NS					
52	3033NS	104	3307NS					

3. Components:

Models A1, B1, B2, B3, D1, D2, D3, F2, F3, F4, F5 and G2 are composed of shell(including upper cover and lower cover), humidified material, filtering material, nut or blank cap. Model F1 is composed of shell(including upper cover and lower cover), humidified material, filtering material and supporting net. Models G1 and G4 are composed of shell(including upper cover and lower cover) and filtering material. Models G3 and I1 are composed of shell(including upper cover and lower cover), filtering material, nut or blank cap. Models C1 and E1 are composed of shell(including upper cover and lower cover) and

CE Technical File	File No: RD/S-115-0002
Disposable Heat and Moisture Exchanger Filters	Rev. No: A/0

humidified material. Model H1 is composed of shell (including upper cover and lower cover), humidified material, connector and oxygen catheter.

4. Intended use:

The product is designed to be used with anesthetic/ breathing circuit, help heat, humidify and filter the breathing air.

5. Performance index:

Item	requirement
Recommended tidal volume	NLT 250 mL
Internal volume	NMT 23.6ml
Gas leakage	25 mL/min
Compliance	3mL/kPa
Moisture loss	NMT 15.0 mg/L @ 250 mL tidal volume NMT 19.5 mg/L @ 500 tidal volume
Pressure drop	NMT 0.2 kPa @ 30L/min flow rate NMT 0.5 kPa @ 60L/min flow rate
Recommended maximum time of use	NMT 24 hrs

6. Directions for use:

- (1) Unpack the package, take out the device.
- (2) Connect the upper cover to the breathing tube, and the lower cover to the mask or tracheal tube.

7. Contraindications:

- (1) Pneumothorax and its mediastinal emphysema without drainage.
- (2) Bullae of lung.
- (3) Hypovolemic shock revamping.
- (4) Severe pulmonary hemorrhage.
- (5) Ischemic heart disease and congestive heart failure.

8. Warning:

- (1) Prohibition of the use of packaging or product damage;
- (2) Prohibition of the use of over expire date;
- (3) Disposable absorbent condensate humidifier is prohibited for repeated use;
- (4) This product should be used under the guidance of professional medical personnel;

CE Technical File	File No: RD/S-115-0002
Disposable Heat and Moisture Exchanger Filters	Rev. No: A/0

(5)The product shall be safely destroyed after use.

9. Transportation & Storage

The device should be stored in a relative humidity NMT 80%, non-corrosive gas and well-ventilated clean environment.

10. Shelf life

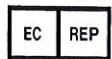
The shelf life is 2 years.



Ningbo Xinwell Medical Technology Co., Ltd.

No.8 Binjiang Road, Cixi High-tech Industrial Development Zone, Cixi City, Zhejiang, 315301, China

Tel: 86-574-63026388; Fax: 86-574-63026388



Lotus NL B.V.

Addr.: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Tel: +31644168999

Email: peter@lotusnl.com

Symbol:

No.	Symbol	Meaning	No.	Symbol	Meaning
1		DATE OF MANUFACTURE	7		BATCH CODE
2		DO NOT REUSE	8		CONSULT INSTRUCTIONS FOR USE
3		CAUTION	9		USE BY
4		MANUFACTURER	10		KEEP AWAY FROM SUNLIGHT
5		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	11		DO NOT USE IF PACKAGE IS DAMAGED
6		THE PRODUCT HAS PASSED CE CERTIFICATION	12		KEEP DRY