
















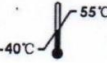
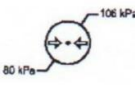


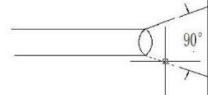


Technical File of  
**UE BRONCHO Single-Use Labelling**  
**Bronchoscopes**









**1. Labelling Description**

Symbol	Title of symbol	For example
Name	Product Name	UE BRONCHO Single-Use Bronchoscopes
Quantity	Product quantity	1 pcs
Working length		mm
Maximum insert portion width		mm
Minimum instrument channel width		mm
Field of view		
	Catalogue number	
	Product model	
	Batch code	
	Date of Manufacture Country of manufacturer	
	Use-by date	
	Do not re-use	
	Do not use if the package is damaged	
	Consult accompanying documents	
	Sterilized using ethylene oxide; Single Sterile barrier system	

Technical File of  
**UE BRONCHO Single-Use Labelling**  
**Bronchoscopes**

Symbol	Title of symbol	For example
	Do not resterilize	
	TYPE BF APPLIED PART	
	Stacking limit by 5	
	This Way UP	
	Fragile, handle with care	
	Caution	
	Keep away from sunlight	
	Keep dry	
	Temperature limit	
	Atmospheric pressure limitation	
	Humidity limitation	
	Medical device	
	Field of view	

Technical File of  
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**Bronchoscopes**

Symbol	Title of symbol	For example
	Working length of the insertion portion	
<b>IPX7</b>	IP Code ( Insertion section )	
	Unique Device Identifier	 <p>(01)01234567891011  (11)200622  (17)240622  (21)88888888</p>  <p>(01)01234567891011(11)200622(17)240622(21)88888888</p>
	Manufacturer	
	Authorized representative in the European Community	
	CE marking of conformity, and Notified Body Code	
	Manufacturer Logo	

## 2. Label sample

### 2.1 Label sample of Primary package

Technical File of  
**UE BRONCHO Single-Use Labelling**  
**Bronchoscopes**

ZHEJIANG UE MEDICAL CORP.

**EN UE BRONCHO Single-Use Bronchoscopes**

only for used together with UE Display and Signal Adapter.

**CAUTION:** The Product should be used or guided for use by healthcare professionals.

Made in China  
Designed by UE Medical

UDI

(01)00000000000000	EBS-380C
(11)000000	: 0000-00-00
(17)000000	: 0000-00-00
(10)B000000	: B00000

(Insertion section) IPX7  
60cm / 23.6"

**ECREP Lotus NL B.V.**  
Koningin Julianaplein 10, 1e Verd. 2595AA,  
The Hague, Netherlands.

**Zhejiang UE Medical Corp.**  
No. 8, Youyi Road, Baita Economic Development Zone,  
Xianju 317300, Zhejiang, China.

ZHEJIANG UE MEDICAL CORP.

**EN UE BRONCHO Single-Use Bronchoscopes**

only for used together with UE Display and Signal Adapter.

**CAUTION:** The Product should be used or guided for use by healthcare professionals.

Made in China  
Designed by UE Medical

UDI

(01)00000000000000	EBS-500C
(11)000000	: 0000-00-00
(17)000000	: 0000-00-00
(10)B000000	: B00000

(Insertion section) IPX7  
60cm / 23.6"

**ECREP Lotus NL B.V.**  
Koningin Julianaplein 10, 1e Verd. 2595AA,  
The Hague, Netherlands.

**Zhejiang UE Medical Corp.**  
No. 8, Youyi Road, Baita Economic Development Zone,  
Xianju 317300, Zhejiang, China.

Technical File of  
**UE BRONCHO Single-Use Labelling**  
**Bronchoscopes**



2.2 Label sample of Middle package



Technical File of  
**UE BRONCHO Single-Use Labelling**  
**Bronchoscopes**

ZHEJIANG UE MEDICAL CORP.

**EN UE BRONCHO Single-Use Bronchoscopes**

only for used together with UE Display and Signal Adapter.

**CAUTION:**  
The Product should be used or guided for use by healthcare professionals.

Slim 3.8/1.2

**QTY: 5 EA**

**UDI**

(01)00000000000000  
 (11)000000  
 (17)000000  
 (10)B000000

**EBS-380C**

0000-00-00  
 0000-00-00  
 B00000

**Made in China**  
Designed by UE Medical

ZHEJIANG UE MEDICAL CORP.

**EN UE BRONCHO Single-Use Bronchoscopes**

only for used together with UE Display and Signal Adapter.

**CAUTION:**  
The Product should be used or guided for use by healthcare professionals.

Regular 5.0/2.2

**QTY: 5 EA**

**UDI**

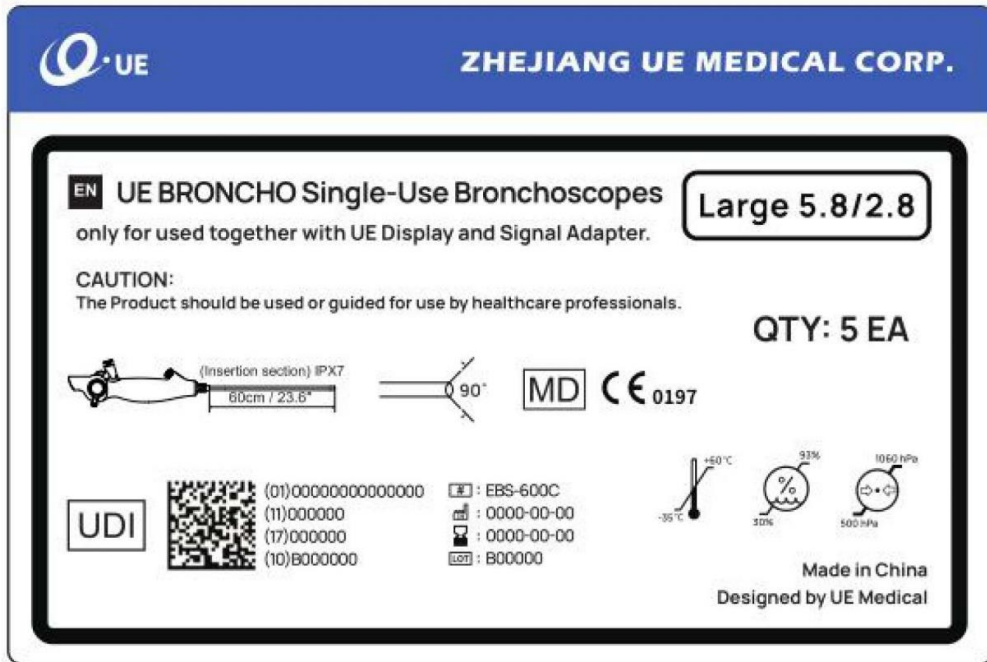
(01)00000000000000  
 (11)000000  
 (17)000000  
 (10)B000000

**EBS-500C**

0000-00-00  
 0000-00-00  
 B00000

**Made in China**  
Designed by UE Medical

Technical File of  
**UE BRONCHO Single-Use Labelling**  
**Bronchoscopes**



2.3 Label sample of Outer package







Zhejiang UE Medical Corp.

No. UE/TPD 4601007

Revision: A2

Effective:

Technical File of  
**UE BRONCHO Single-Use Labelling**  
**Bronchoscopes**

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**Q·UE** **ZHEJIANG UE MEDICAL CORP.**

**EN UE BRONCHO Single-Use Bronchoscopes**

only for used together with UE Display and Signal Adapter.

**CAUTION:**  
The Product should be used or guided for use by healthcare professionals.

MD CE 0197

(Insertion section) IPX7  
60cm / 23.6"

90°

UDI

(01)00000000000000  
(11)000000  
(17)000000  
(10)B000000

EBS-380C  
0000-00-00  
0000-00-00  
B00000

**Slim 3.8/1.2**

**50(Pcs)**  
G.W : 00.00Kg  
N.W : 00.00Kg

**MEAST:**  
920 × 625 × 620 mm

Made in China  
Designed by UE Medical

**Q·UE** **ZHEJIANG UE MEDICAL CORP.**

**EN UE BRONCHO Single-Use Bronchoscopes**

only for used together with UE Display and Signal Adapter.

**CAUTION:**  
The Product should be used or guided for use by healthcare professionals.

MD CE 0197

(Insertion section) IPX7  
60cm / 23.6"

90°

UDI

(01)00000000000000  
(11)000000  
(17)000000  
(10)B000000

EBS-500C  
0000-00-00  
0000-00-00  
B00000

**Regular 5.0/2.2**

**50(Pcs)**  
G.W : 00.00Kg  
N.W : 00.00Kg

**MEAST:**  
920 × 625 × 620 mm

Made in China  
Designed by UE Medical





Zhejiang UE Medical Corp.

Technical File of
UE BRONCHO Single-Use Labelling
Bronchoscopes

Label for UE BRONCHO Single-Use Bronchoscopes, Large 5.8/2.8. Includes technical specifications, caution, and UDI information.

2.4 Label of paper plastic pouch

Instructions for Use section containing 8 numbered diagrams and corresponding text instructions for check and preparation, insertion, liquid injection, suction, photo shooting and video recording, and device removal.

2.5 Label of Model

Label for UE BRONCHO Single-Use Bronchoscopes, Model 3.8/1.2

Label for UE BRONCHO Single-Use Bronchoscopes, Model 5.0/2.2

Label for UE BRONCHO Single-Use Bronchoscopes, Model 5.8/2.8