



# BQ PLUS MEDICAL CO., LTD

No.18, Che Ye Road, CheDun Town, Songjiang Shanghai 201611 CHINA

Tel: 0086-21-57609106 [http:// www.bqplusmedical.com](http://www.bqplusmedical.com)

## Technical Specification

**Title (Description):** Extension Sets

**Vendor Name/Code:** BQ PLUS MEDICAL CO.,LTD

**Class:** Is

**UMDNS-Code:** 12157

### Standards:

The applicable harmonized standards:

ISO 8536-4: Infusion equipment for medical use- Part 4:Infusion sets for single use, gravity feed

ISO 80369-7: Small-bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for intravascular or hypodermic applications

ISO14971: Medical Devices- Application of risk management to medical device

ISO13485: Medical Devices- Quality management systems – Requirements for regulatory purposes

### 1. Contract Manufacturer

BQ PLUS MEDICAL CO.,LTD

No.18, Che Ye Rd, Che Dun Town, Songjiang District, Shanghai 201611, China

### 2. Product Information

No.	Product code	Product information	Put-Up Qty
1	BQES23152	Extension Sets	1pcs/Pouch,50pcs/bag,300pcs/Box

#### 2.1 Component Descriptions

Items	Component and/or Description	Material	Color	Remark
Material 1	Cap (HT152-W-02)	PE	White	
Material 2	Female Luer Lock(FLL01-4.0)	PC	Transparent	
Material 3	Tube 160mm(2.9*4.05mm)	DEHP FREE PVC	Transparent	
Material 4	Precision Filter(ATT-0.2-HT)	ABS,PES,PTFE	Transparent	
Material 5	Tube 160mm(2.9*4.05mm)	DEHP FREE PVC	Transparent	
Material 6	Male luer lock(MLL04-4.0-01)	ABS	Transparent	
Material 7	Cap (HT104)	PE	Natural	
Contain natural rubber latex or not		No		

#### 2.2 Product Dimension

Component name	Tolerance	Tolerance (±5g)	Tolerance (± 0.07mm)
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REV.: TDS002171A

Date: 2024.09.19

	Total Length(mm)	Weight(g)	I.D*O.D
BQES23152	390-420	16.2	2.9*4.05



**2.3 Others (Product function, performance, weight capacity, electric parameter and so on.)**

2.3.1 The complete set:

- 2.3.1.1 It can connect with male luer lock of infusion set.
- 2.3.1.2 The tube is made from DEHP free PVC.
- 2.3.1.3 Tensile strength > 15N/15S.
- 2.3.1.4 The set can hold up to 2bar.
- 2.3.1.5 Priming volume approximately 3.76ml.
- 2.3.1.6 Total set length: approximate 39cm.
- 2.3.1.7 The set is possible to work with FMS.

2.3.2 The filter:

- 2.3.2.1 Filtration area 10cm<sup>2</sup>, antibacterial filter.
- 2.3.2.2 Priming volume is approximately 1.87ml.
- 2.3.2.3 Max operating pressure 3.2 bar.
- 2.3.2.4 Minimum water flow rate 30ml/min.
- 2.3.2.5 Usage duration up to 24 hours

**2.4 Testing & Inspection Criteria**

Testing shall be per contract manufacturers final test procedures. The vendor must provide the Certificate of Sterilization (COS) / Certificate of Compliance (COC) / Analysis (COA) if applicable for all the items shipped.

**3. Packaging**

**3.1 Inner Package**  Applicable /  Not Applicable

3.1.1 Type (Please choose from below item)

<input type="checkbox"/> Bag	<input checked="" type="checkbox"/> Pouch	<input type="checkbox"/> Box	<input type="checkbox"/> Blister	<input type="checkbox"/> Canister
<input type="checkbox"/> Tray	<input type="checkbox"/> Bottle	<input type="checkbox"/> Others (Please write details):		

3.1.2 Material (Please choose from below item)

<input type="checkbox"/> Paper	<input type="checkbox"/> Plastic	<input checked="" type="checkbox"/> Paper & Plastic	<input type="checkbox"/> Others (Please write details):
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3.1.3 Dimension

Reorder #	Tolerance (±5mm)			Tolerance (± mm)	Put-Up Qty
	Length(mm)	Width(mm)	Height(mm)	O.D(mm)	
BQES23152	210	130	N/A	/	1pcs



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### 3.2 Middle Package( Applicable/ Not Applicable)

#### 3.2.1 Type(Please choose from below item)

<input type="checkbox"/> Box	<input checked="" type="checkbox"/> Bag	<input type="checkbox"/> Others(Please write details):
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#### 3.2.2 Material(Please choose from below item)

<input type="checkbox"/> Paper	<input checked="" type="checkbox"/> Plastic	<input type="checkbox"/> Paper&Plastic	<input type="checkbox"/> Others(Please write details):
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#### 3.2.3 Dimension

Reorder #	Tolerance (± mm)			Put-Up Qty
	Length(mm)	Width(mm)	Height(mm)	
BQES23152	550	450	NA	50pcs

### 3.3 Outer Package( Applicable/ Not Applicable)

#### 3.3.1 Type(Please choose from below item)

<input type="checkbox"/> A corrugate	<input type="checkbox"/> B corrugate	<input type="checkbox"/> Ecorrugate	<input checked="" type="checkbox"/> A+B
<input type="checkbox"/> B+B	<input type="checkbox"/> B+E	<input type="checkbox"/> Others(Please write details):	

#### 3.3.2 Material(Please choose from below item)

<input type="checkbox"/> Three layers corrugated	<input checked="" type="checkbox"/> Five layers corrugated	<input type="checkbox"/> Others(Please write details):
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#### 3.3.3Dimension

Reorder #	Tolerance (±10mm)			Put-Up Qty
	Length(mm)	Width(mm)	Height(mm)	
BQES23152	400	300	360	300pcs

### 3.4 Others Package Level ( Applicable/ Not Applicable)

#### 3.4.1 Type PALLET

3.4.2 Material  Composite board  Others

3.4.3 Dimension  110\*100mm  120\*100mm  Others

## 4. Sterilization

N/A

EO

## 5. Shelf life or Warranty

Shelf is (5) years.

REV.	DESCRIPTION	DATE	REMARK
A0	Initial Release	2024.09.19	