



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	BQES24221	Extension Sets	1pcs/Pouch,50pcs/Bag,300pcs/Box

2.1 Component Descriptions

Items	Component and/or Description	Material	Color	Remark
Material 1	Cap	PE	Natural	
Material 2	Female luer lock	ABS	Transparent	
Material 3	Tube 1500mm(1.5*3.0mm)	DEHP FREE PVC	Yellow	
Material 4	Male luer lock	ABS	Transparent	
Material 5	Cap	PE	Natural	
Contain natural rubber latex or not		No		

2.2 Product Dimension

Component name	Tolerance	Tolerance (±5g)	Tolerance (± 0.07mm)
	Total Length(mm)	Weight(g)	I.D*O.D
BQES24221	1500-1550	x	1.5*3.0

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

- 2.3.1 Gravity use
- 2.3.2 1.5*3.0mm PVC tubing
- 2.3.3 DEHP-Free, Non-toxic, Pyrogen free
- 2.3.4 Tensile strength > 15N/15S
- 2.3.5 6% distal end male luer lock and female luer lock compliance ISO 80369-7 standard
- 2.3.6 With protective caps on both ends
- 2.3.7 Pressure resistance up to 7bar
- 2.3.8 Light Resistant

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):
--------------------------------	----------------------------------	---	--

3.1.3 Dimension

Reorder #	Tolerance (±5mm)			Tolerance (± mm)	
	Length(mm)	Width(mm)	Height(mm)	O.D(mm)	Put-Up Qty
BQES24221	230	130	N/A	/	1pcs

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):
------------------------------	---	--

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):
--------------------------------	---	--	--

3.2.3 Dimension

Reorder #	Tolerance (± mm)			Put-Up Qty
	Length(mm)	Width(mm)	Height(mm)	
BQIV24221	550	450	N/A	50pcs

3.3 Outer Package(Applicable/ Not Applicable)

3.3.1 Type(Please choose from below item)



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)

<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):
--	--	---

3.3.3 Dimension

Reorder #	Tolerance (± 10 mm)			Put-Up Qty
	Length(mm)	Width(mm)	Height(mm)	
BQES24221	395	295	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
A	Initial Release	2024.09.03	