



## FL MEDICAL TECHNICAL DATA SHEET:

### BCS Blood Collection Set ( PSV+ LM )

#### 1.ProductReference

Reference	Needle Diameter	Needle length	Tubing length	Color code of wing hub	Priming Volume	Flow rate
45301	21 G (0.8 mm)	¾'' (19 mm)	300 mm	Green	0.44 ml	26.6 ml/min
45302	22 G (0.7 mm)	¾'' (19 mm)	300 mm	Black	0.44 ml	16.0 ml/min
45303	23 G (0.6 mm)	¾'' (19 mm)	300 mm	Blue	0.44 ml	9.2 ml/min

Air leakage test: >3.0 kgf/cm<sup>2</sup>.G (43 psi)

Remark: standard products, type Cannula Bevel Short length

#### 3.Material

All Materials used to produce our BCS Blood Collection Set are Medical Grade, latex-free. Non-DEHP and kink resistant tubing.

Part Name	Material
PSV:	
Protector, EL luer cap	Polypropylene
Needle	Stainless steel SUS-304
Wing hub, tube	PVC, non-DEHP
Cp luer connector	ABS
Glue	Epoxy
Luer adapter:	
Hub	Polypropylene
Rubber seal	Synthetic rubber
Cannula	Stainless steel SUS-304

#### 4.Printing

Graphical symbols for use in the labeling of medical devices are designed according to the EN 15223-1: 2012

#### 5.Packaging

Sterility is ensured by an individual package and a chemical indicator which is stucked on an external carton. Unit pack is made of Ribbon Tape and OPP/PE film , inner box is made of Duplex board, and outer box is made of double corrugated board.



Each packaging unit contains the lot number information, shelf life information, sterilization information.

Product name	Individual package		Inner box				Outer carton			
	<u>L</u>	<u>W</u>	<u>L</u>	<u>W</u>	<u>H</u>	<u>QTY</u>	<u>L</u>	<u>W</u>	<u>H</u>	<u>QTY</u>
Blood Collection Set	100	108	197	108	103	50 pcs	537	452	226	1000 pcs

All sizes in the above table are indicated in mm

An individual package contains one set of BCS Blood Collection Set

An inner box contains 50 individual packages of BCS Blood Collection Set

An outer box contains 10 inner boxes of BCS Blood Collection Set (1000 individual packages)

Each packaging unit contains the lot number information, shelf life information, sterilization information.

## 6.Packprinting

Labels contain 12 languages and have been designed according to the specifications of:

- European Medical Device directive
- FDA

Languages are: English, French, Dutch, German, Spanish, Italian, Portuguese, Greek, Swedish, Danish, Norwegian, and Finish.

## 7.Quality

Produced in ISO 9001:2008 and EN ISO 13485:2012 certified facilities.  
Sterile hypodermic needles for single use comply with ISO 7864: 1993

Sterilized by ETO 

## 8.Characteristics

Non-slipping structure on wing of device (easy to insert the device into the vein without any slipping at penetrating it).

Color coding for identification is made according to ISO 6009: 1998.

- 3 years shelf life 
- Single use 

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