

	Product Technical Data		

## Product Technical Data

Product Name I PR SA O M r d d

### Item Code, specification, color code and package information

Product Code	Description	Needle Gauge Needle Length(Inches) Tubing Length(Inches)	ing Cd or shield color	Bo Carton ty
<b>I PR SA ultisample Needle( IT PR ATTAC D LD R)</b>				
1	ulti sample Needle	G 1	ellow	
1	ulti sample Needle	G 1	ellow	
1 1	ulti sample Needle	1G 1	Green	
1 1	ulti sample Needle	1G 1	Green	
1	ulti sample Needle	G 1	Black	
1	ulti sample Needle	G 1	Black	
1	ulti sample Needle	G 1	Blue	
1	ulti sample Needle	G 1	Blue	

Note the specification is not limited to the above table Refer to product list for full specification

### Subject and application

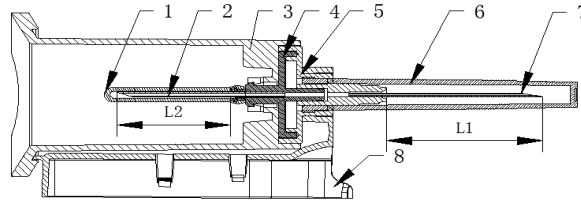
The products and evacuated blood collection tubes are used together for the collection of venous blood. The products are designed with a safety shield which can be activated to cover the needle immediately following blood collection to aid in the protection against accidental needle stick injury. The attached holder is designed to aid in protection against accidental needle injury and blood splatter. It also helps to improve the working efficiency as it eliminates the procedure of holder assembling. The flashback is designed to sign a venipuncture success. It also helps to add reassurance of flashback for the confidence of success.

The products are single use, sterile, non pyrogenic

### Product photo



## Structure and raw material



- 1 rubber sleeve nature isoprene synthetic rubber  
 tube needle

## Specification of needle

Conform to the specification of the following table (Refer to GB1 11 for diameter specification )

Table 1 Unit : mm

Type	Size	uter diameter		Inner diameter
		in	a	in
ein end needle	( G )			
	( G )			
	( G )			
	( 1G )			
	( G )			

### Needle length, needle bevel angle

Type	Needle Nominal ID length L(mm)	Limit deviation (mm)	Bevel angle a	Note
ein end needle	L<	+1 —	Short Bevel angle 1	
	L<	+1 —		
	L=	—	Long Bevel angle	

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	>	+		
		-		

### Raw material certifications

All raw materials used are non toxic, food and medical certified, as per European and FDA (USA) directives

### Shelf life

Three years from manufacturing date

### Storage

Store needles under room temperature and room well ventilated and without corrosive gas

### Shipping Information

Normal shipping Normal dry container













### Sterilization

The needle is sterilized by ethylene oxide, sterile, non toxic, non pyrogenic, non hemolytic reaction

### Disposal modality

Before the use the products are to be considered not hazardous materials. After the use become medical waste potentially infected that have to be collect and disposed applying all particular precautions to avoid infections

### Information on the label and symbols

Symbol and Mark Key			
	Single Use		Latex Free
	Expiry Date		Catalog Number
	Batch Code		Keep Away from Sunlight
	Sterile		Manufacturer
	Authorized Representative		Consult Instructions for Use
	Method of Sterilization (ethylene oxide)		Date of Manufacture

### General applicable directives

EU Quality Management System Certificate (MDR): Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

### Standard Applied

EN ISO 13485:2016/AC:2018	EN ISO 14971:2019	EN ISO 7864:2016
EN ISO 9626:2016	EN ISO 23908:2013	EN ISO 80369-7:2017
EN ISO 11135:2014/A1:2019	EN ISO 11607-1:2020	EN ISO 11607-2:2020
EN ISO 15223-1:2016	EN ISO 20417:2021	EN ISO 10993-1:2020
EN ISO 10993-4:2017	EN ISO 10993-5:2009	EN ISO 10993-7:2008/AC:2009
EN ISO 10993-10:2013	EN ISO 10993-11:2018	ASTM D4169-16
ASTM F1980-16		

