



ISO 13485

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Company profile

Giglioli Fabrizio and Medcom srl were born in Rovereto sulla Secchia in the north of Italy in the centre of the Italian production of plastic devices for the medical and biomedical sectors, with the objective of providing high quality products.

Giglioli Fabrizio was born in 1989 inside the garage of his family house with a couple of small moulding machines. Over the following years with the collaboration of a local company (Lameplast) an establishment of 300 m² for the production, where the company moved, and a warehouse of 150 m² beside it were purchased in 1993 and in 1994 was introduced a laboratory in 10 Battisti Street to add new machines.

During 1999 the company moved again for further expansion of its machines fleet and division of the departments "Assembly" and "Moulding" to 36 and 1/A Carducci Street.

Giglioli Fabrizio srl - lavorazioni materie plastiche (Giglioli Fabrizio Ltd – working plastic materials) founded in 1989 and became Ltd in 2013 is a client-oriented company which offers:

Production of moulded and pre-assembled components for medical and pharmaceutical devices, also on specification by the client with exclusivity for the client

Production and distribution of medical devices for:

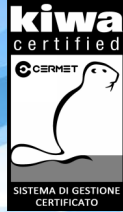
- draining systems
- suction tubes
- thoracentesis and paracentesis kits
- bags for urine and waste
- system for the measurement of hourly diuresis "Misuro"
- suction/aspiration cannulas
- wash sets
- accessories for medical devices packaged in blisters
- production and assembly of medical devices on client request
- small bottle with or without serigraphy / labeling

The production area of Giglioli Fabrizio are subdivided into 2 macro areas, 1 for 'moulding' of about 2100 m² and 1 for 'assembly' of about 700 m², both situated in Rovereto sulla Secchia, a few metres from each other.

All our productions are performed in clean rooms certified ISO 8 which are designed and created with techniques able to satisfy the clients' quality requests through the use of modern and advanced constructive techniques.

In the moulding area there are n°12 moulding machines with a closing pressure of 40 to 200 tons, 3 injection-blowing machines, 2 injection-stretch-blowing machines for PET and 3 extrusion-blowing machines.

In both departments the packaging of the product is done in a dedicated clean room in order to optimize the cleanliness and the quality of the work



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Inside the company there is an internal quality control that performs daily checks of all productions with advanced tools and qualified staff.

Some dates:

1989: year of foundation and start of production

1993: moved in a new building/factory and warehouse in 36 Battisti Street

1994: installation to a laboratory

1999: company moved to 1A and 36 Carducci Street and division in Assembly and Moulding depts. for further expansion

Jan 2012: moved to a 19 Montale street in a building of over 4000 m2

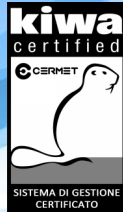
2012: Acquisition of Medcom srl

May 2012: earthquake with smash new company location

July 2012: return to the previous establishment in Carducci street with expansion of clean rooms and with the addition of another 500 m2 of warehouse

May 2013: CE certification for the production of our final products

Summer 2015: CE adding new products and ISO 13485 certification



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Components





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1. Male adaptors



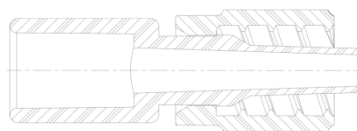


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1.1 Rotating male luer lock

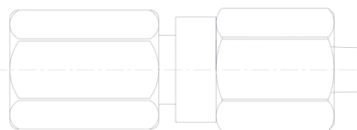
Rotating male luer lock for tube Ø 6.8 mm
Material: Rigid PVC - PC / STD Pack: 10.000 pcs

A00109990 - ETO (Neutral)
A00109992 - ETO (Red)
A00109993 - ETO (Blue)
A00109980 - Radiation (Neutral)
A00109982 - Radiation (Red)
A00109983 - Radiation (Blue)



Rotating male luer lock for tube Ø 5.5 mm
Material: Rigid PVC - PC / STD Pack: 10.000 pcs

A00119990 - ETO (Neutral)
A00119992 - ETO (Red)
A00119993 - ETO (Blue)
A00119980 - Radiation (Neutral)
A00119982 - Radiation (Red)
A00119983 - Radiation (Blue)



Rotating male luer lock for tube Ø 4.1 mm
Material: Rigid PVC - PC / STD Pack: 10.000 pcs

A00129990 - ETO (Neutral)
A00129992 - ETO (Red)
A00129993 - ETO (Blue)
A00129980 - Radiation (Neutral)
A00129982 - Radiation (Red)
A00129983 - Radiation (Blue)

• Dimension: "mm"



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1.2 Fixed male luer lock vented cap

Male luer lock with vented cap for tube Ø 2.0 mm Material: ABS - LDPE / STD Pack: 10.000 pcs A01409990 - ETO - Radiation	
Male luer lock with vented cap for tube Ø 2.5 mm Material: ABS - LDPE / STD Pack: 10.000 pcs A01419990 - ETO - Radiation	
Male luer lock with vented cap for tube Ø 3.2 mm Material: ABS - LDPE / STD Pack: 10.000 pcs A01479990 - ETO - Radiation	
Male luer lock with vented cap for tube Ø 3.7 mm Material: ABS - LDPE / STD Pack: 10.000 pcs A01489990 - ETO - Radiation	
Male luer lock with vented cap for tube Ø 4.1 mm Material: ABS - LDPE / STD Pack: 10.000 pcs A01429990 - ETO - Radiation	
Male luer lock with vented cap for tube Ø 5.5 mm Material: ABS - LDPE / STD Pack: 10.000 pcs A01449990 - ETO - Radiation	
Male luer lock with vented cap for tube Ø 6.8 mm Material: ABS - LDPE / STD Pack: 10.000 pcs A01459990 - ETO - Radiation	

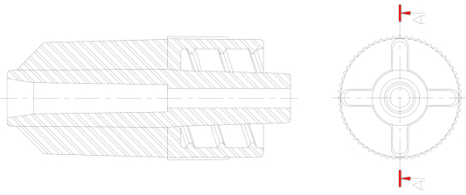
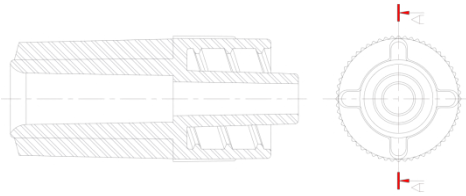
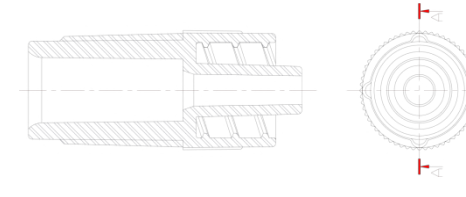
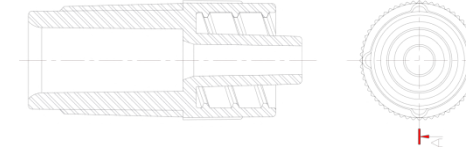
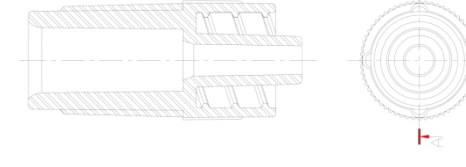
• Dimension: "mm"





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1.3 Fixed male luer lock

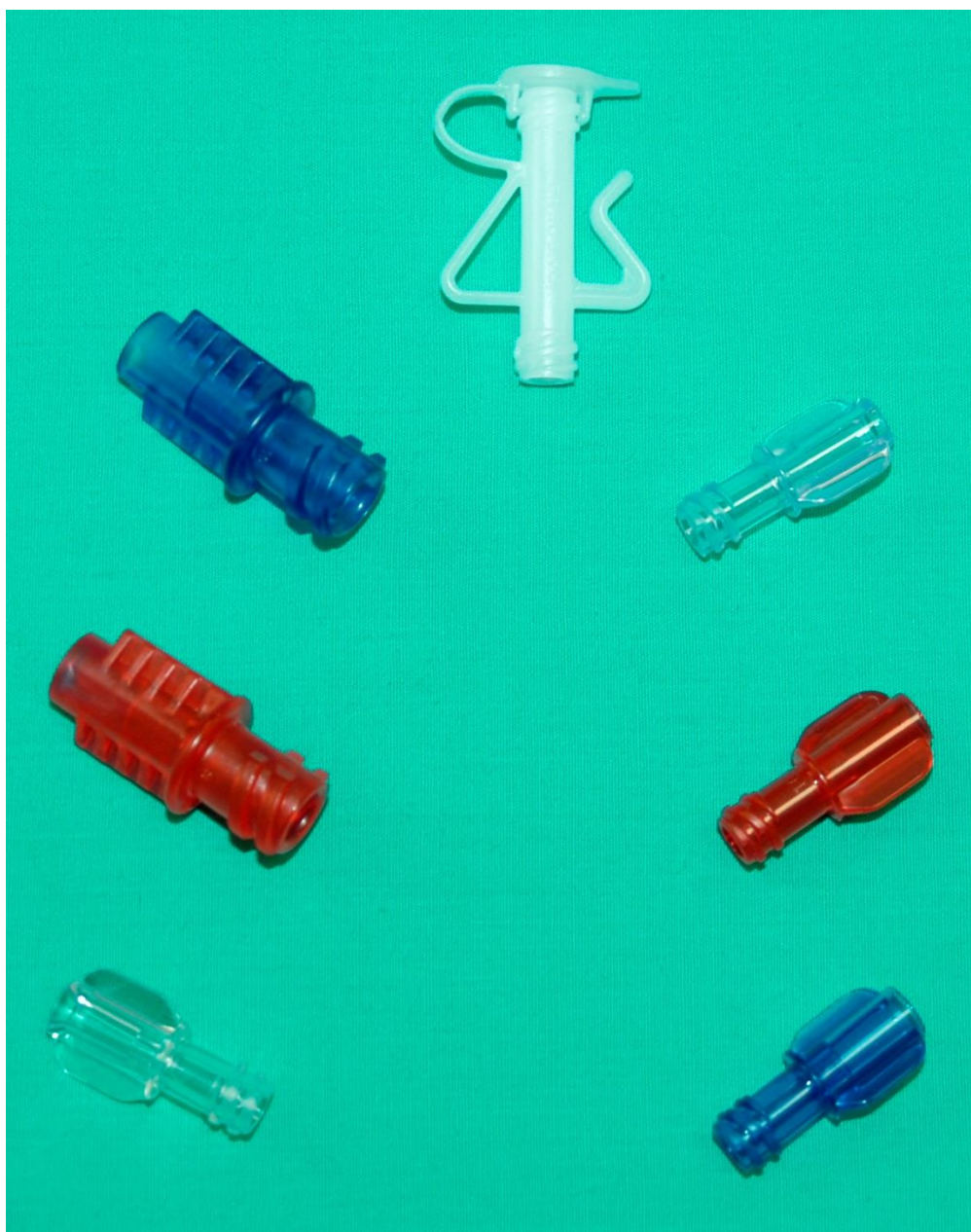
<p>Male luer lock for tube Ø 2.0 mm Material: ABS / STD Pack: 20.000 pcs</p> <p>C13304020 - ETO - Radiation</p> <p>Male luer lock for tube Ø 2.5 mm Material: ABS / STD Pack: 20.000 pcs</p> <p>C13314020 - ETO - Radiation</p>	
<p>Male luer lock for tube Ø 3.2 mm Material: ABS / STD Pack: 20.000 pcs</p> <p>C13374020 - ETO - Radiation</p> <p>Male luer lock for tube Ø 3.7 mm Material: ABS / STD Pack: 20.000 pcs</p> <p>C13384020 - ETO - Radiation</p>	
<p>Male luer lock for tube Ø 4.1 mm Material: ABS / STD Pack: 20.000 pcs</p> <p>C13324020 - ETO - Radiation</p>	
<p>Male luer lock for tube Ø 5.5 mm Material: ABS / STD Pack: 20.000 pcs</p> <p>C13344020 - ETO - Radiation</p>	
<p>Male luer lock for tube Ø 6.8 mm Material: ABS / STD Pack: 20.000 pcs</p> <p>C13354020 - ETO - Radiation</p>	

• Dimension: "mm"



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2. Female adaptors





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2.1 Female luer lock

Female luer lock for tube \varnothing 2.1 mm
Material: Rigid PVC / STD Pack: 15.000 pcs

C11011030 - ETO
C11018010 - Radiation

Female luer lock for tube \varnothing 2.5 mm
Material: Rigid PVC / STD Pack: 15.000 pcs

C11021030 - ETO
C11028010 - Radiation

Female luer lock for tube \varnothing 3.2 mm
Material: Rigid PVC / STD Pack: 15.000 pcs

C11081030 - ETO
C11088010 - Radiation

Female luer lock for tube \varnothing 3.7 mm
Material: Rigid PVC / STD Pack: 15.000 pcs

C11071030 - ETO
C11078010 - Radiation

Female luer lock for tube \varnothing 4.1 mm
Material: Rigid PVC / STD Pack: 15.000 pcs

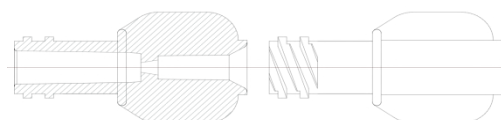
C11031030 - ETO
C11038010 - Radiation

Female luer lock for tube \varnothing 5.0 mm
Material: Rigid PVC / STD Pack: 15.000 pcs

C11091030 - ETO
C11098010 - Radiation

Female luer lock for tube \varnothing 5.5 mm
Material: Rigid PVC / STD Pack: 15.000 pcs

C11041030 - ETO
C11048010 - Radiation

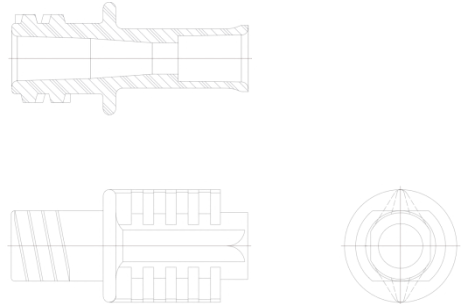
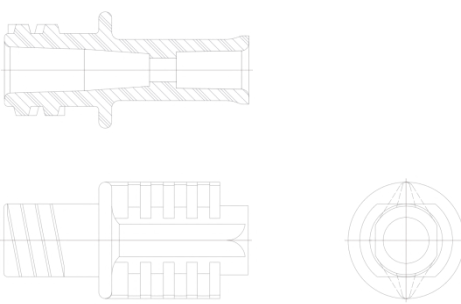
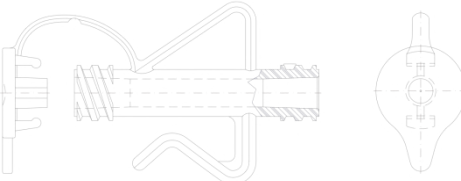


• Dimension: "mm"

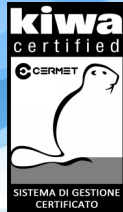


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2.2 Female dialyser connector

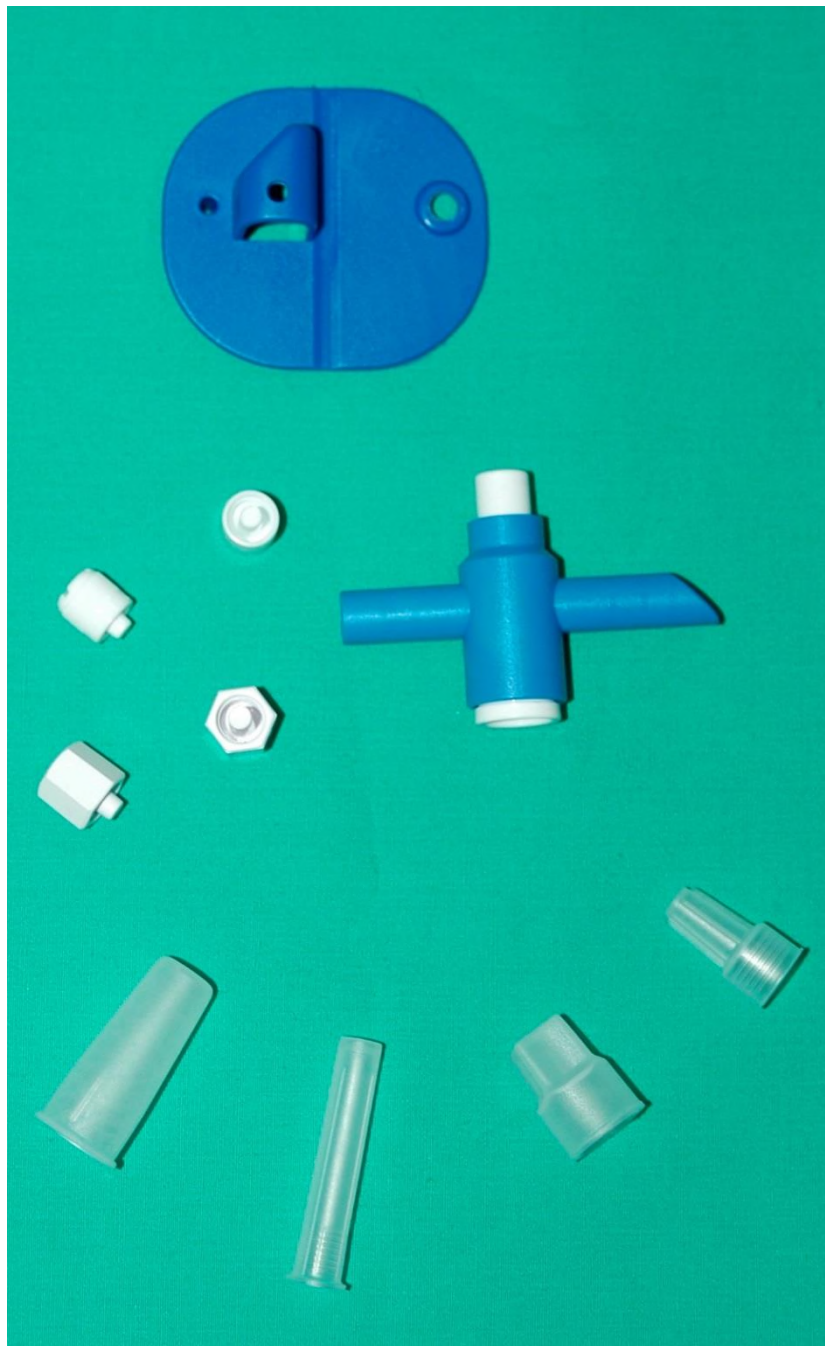
<p>Female dialyser connector for tube \varnothing 6.8 mm Material: Soft PVC / STD Pack: 4.000 pcs</p> <p>C10900030 - ETO - Radiation (Neutral) C10900032 - ETO - Radiation (Red) C10900033 - ETO - Radiation (Blue)</p>	
<p>Female dialyser connector for tube \varnothing 5.5 mm Material: Soft PVC / STD Pack: 4.000 pcs</p> <p>C10910030 - ETO - Radiation (Neutral) C10910032 - ETO - Radiation (Red) C10910033 - ETO - Radiation (Blue)</p>	
<p>Recirculating adapter with closed vented cap Material: HDPE / STD Pack: 6.000 pcs</p> <p>C11102120 - ETO - Radiation</p>	

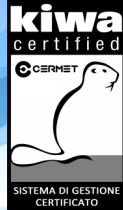
• Dimension: "mm"



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3. Capping devices



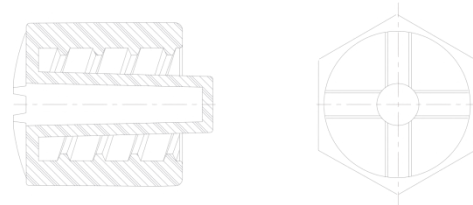


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3.1 – Capping devices

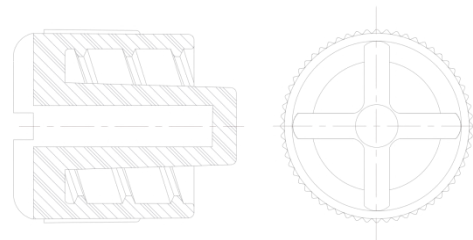
Closed cap male luer lock
Material: ABS / STD Pack: 20.000 pcs

C10304121 - ETO - Radiation (White)



Closed cap male luer lock
STD Pack: 30.000 pcs


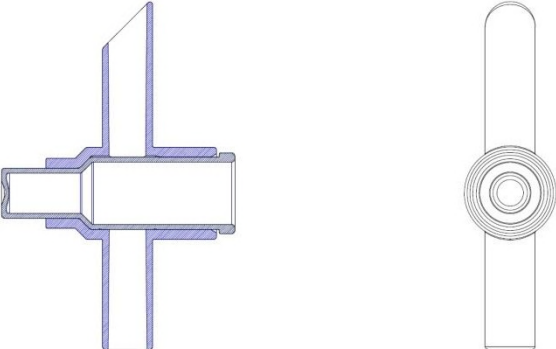
C10402120 - ETO - Radiation (Natural) LDPE
C10402121 - ETO - Radiation (White) LDPE
C10404121 - ETO - Radiation (White) ABS
C10404145 - ETO - Radiation (Green) ABS





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3.2 – T Valve

<p>Rigid support for stopcock Material: PE / STD Pack: 3.000 pcs 7120120102 - ETO - Radiation (Blue)</p>	
<p>T valve for urine bag Materiale: PVC – HDPE Pack: 1.500 pcs M206001000 – ETO</p>	

• Dimension: "mm"

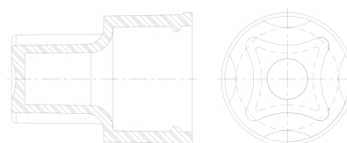


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3.3 – Protective Cap

Vented cap for rotating male luer lock and dialyser connector (for item A001, C109)
Material: LDPE / STD Pack: 10.000 pcs

C10602020 - ETO - Radiation (Neutral)
C10602022 - ETO - Radiation (Red)
C10602023 - ETO - Radiation (Blue)



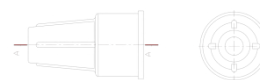
Vented cap for 1 way spike (for spike C134)
Material: LDPE / STD Pack: 10.000 pcs

C16502020 - ETO - Radiation (Neutral)



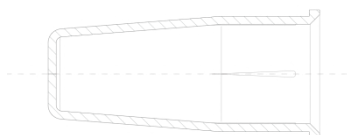
Vented cap for fixed male luer lock (for item C133)
Material: LDPE / STD Pack: 15.000 pcs

C16702130 - ETO - Radiation (Neutral)



Protective cap, 12.4 mm diameter (for catheter cone Ø 8.0 / Ø 9.8 mm)
Material: LDPE / STD Pack: 5.000 pcs

7121070000 - ETO - Radiation (Neutral)





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4. Clamping devices



Giglioli Fabrizio S.r.l. Via Carducci 1/A - 41016 Rovereto s/S (MO) - Italy - P.Iva/C.F. 03492440361
Tel. +39.059.67.24.96 - Fax +39.059.67.22.72 - Web: www.medcomsrl.it Email: info@gigliolifabrizio.it



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4.1 - Clamp

Small clamp on/off for tubes \varnothing 4.1 mm / \varnothing 5.5 mm
Material: PP / STD Pack: 8.000 pcs

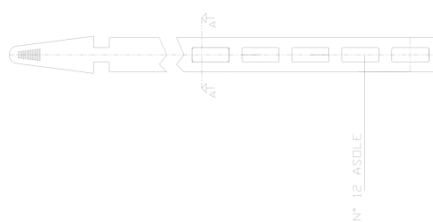
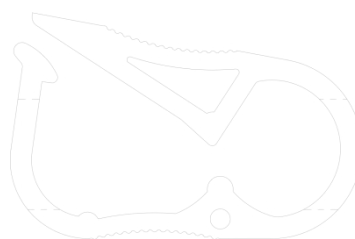
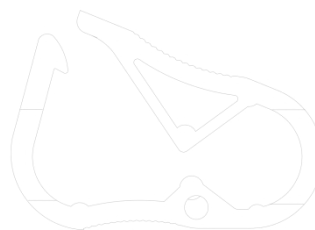
C13203131 - ETO - Radiation (Neutral)
C13203132 - ETO - Radiation (Red)
C13203133 - ETO - Radiation (Blue)

Medium clamp on/off for tubes \varnothing 5.5 mm / \varnothing 6.8 mm
Material: PP / STD Pack: 3.000 pcs

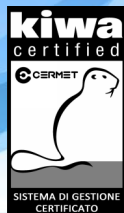
C13503131 - ETO - Radiation (Neutral)
C13503132 - ETO - Radiation (Red)
C13503133 - ETO - Radiation (Blue)

Adjustable hose clamp, 1.5 x 12 mm
length 355 mm
Material: LDPE / STD Pack: 4.000 pcs

7152001402 - ETO - Radiation (Blue)


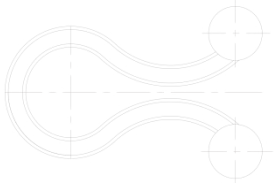
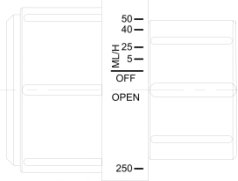
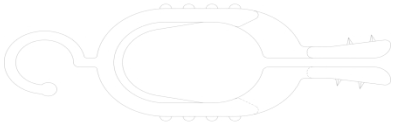


• Dimension: "mm"



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4.2 - Clip-out and Flow regulator

<p>Mini heparine clip STD Pack: 25.000 pcs</p> <p>C12501030 - ETO (Neutral) Rigid PVC C12502120 - ETO - Radiation (Neutral) HDPE</p>	
<p>Medium heparine clip STD Pack: 25.000 pcs</p> <p>C12601030 - ETO (Neutral) PVC C12602120 - ETO - Radiation (Neutral) HDPE</p>	
<p>Lam flow regulator "0 / 250 ml" tube Ø 4.1 mm for gravity infusion Material: ABS - Synthetic Rubber / STD Pack: 1.000 pcs</p> <p>M201001XXX - ETO - Radiation (white)</p>	
<p>Clamp sheet for bag Material: ABS / STD Pack: 4.000 pcs</p> <p>7140281409 - ETO - Radiation (Blue)</p>	



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4.2 - Clip-out and Flow regulator

Open slide clamp for tubes
Material: ABS / STD Pack: 5.000 pcs
7141211409 - ETO - Radiation (Blue)



• Dimension: "mm"



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5. Connectors



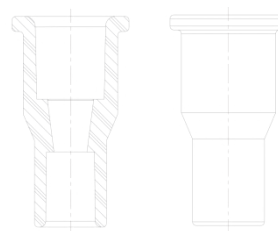


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5.1 - Pump connectors \varnothing 9.54 mm

Pump connector \varnothing 9.54 mm
for tube \varnothing 6.8 mm straight
Material: Soft PVC (*NO-DOP) / STD Pack: 6.000 pcs

C10000030 - ETO - Radiation



• Dimension: "mm" • All components in Soft PVC are available in NO-DOP too



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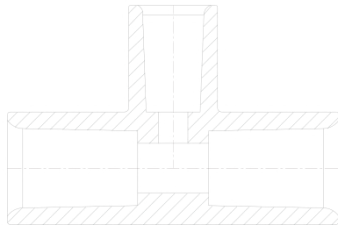
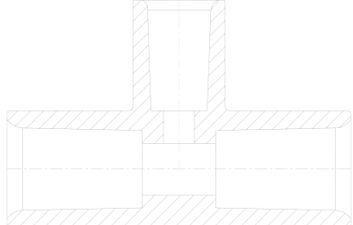

5.2 - Pump connectors Ø 12 mm

<p>Pump connector Ø 12.0 mm for tube Ø 6.8 mm straight Material: Soft PVC (*NO-DOP) / STD Pack: 4.000 pcs C10500030 - ETO - Radiation</p>	
<p>Pump connector Ø 12.0 mm for tube Ø 6.8 mm heparine Ø 2.0 mm Material: Soft PVC (*NO-DOP) / STD Pack: 4.000 pcs C10510030 - ETO - Radiation</p>	
<p>Pump connector Ø 12.0 mm for tube Ø 6.8 mm heparine Ø 2.5 mm Material: Soft PVC (*NO-DOP) / STD Pack: 4.000 pcs C10520030 - ETO - Radiation</p>	
<p>Pump connector Ø 12.0 mm for tube Ø 6.8 mm heparine Ø 4.1 mm Material: Soft PVC (*NO-DOP) / STD Pack: 4.000 pcs C10530030 - ETO - Radiation</p>	
<p>Pump connector Ø 12.0 mm for tube Ø 6.8 mm heparine Ø 5.5 mm Material: Soft PVC (*NO-DOP) / STD Pack: 4.000 pcs C10540030 - ETO - Radiation</p>	



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5.2 - Pump connectors Ø 12 mm

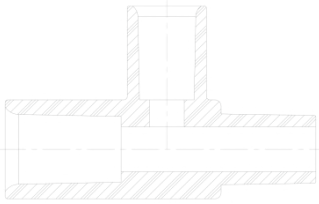
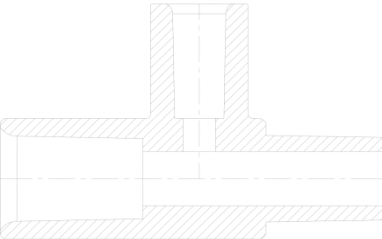

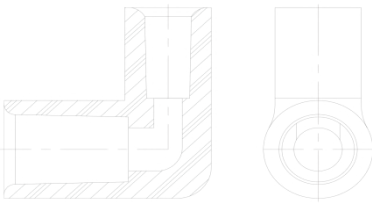
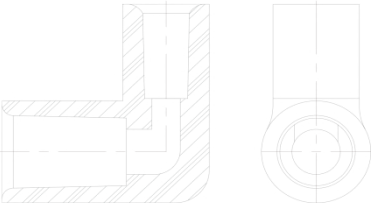
<p>“T” connector for tube Ø 6.8 mm heparine Ø 5.5 mm Material: Soft PVC (*NO-DOP) / STD Pack: 8.000 pcs</p> <p>C11500030 - ETO - Radiation</p>	
<p>“T” connector for tube Ø 6.8 mm heparine Ø 4.1 mm Material: Soft PVC (*NO-DOP) / STD Pack: 8.000 pcs</p> <p>C11510030 - ETO - Radiation</p>	
<p>“T” connector for tube Ø 6.8 mm heparine Ø 3.7 mm Material: Soft PVC (*NO-DOP) / STD Pack: 8.000 pcs</p> <p>C11540030 - ETO - Radiation</p>	

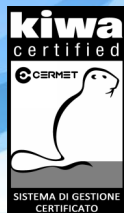
Dimension: “mm” • All components in Soft PVC are available in NO-DOP too



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5.4 - Suction and Hansen connectors

<p>“T” connector 1 female for tube Ø 6.8 mm + 1 male for tube Ø 6.8 mm heparine Ø 5.5 mm Material: Soft PVC (*NO-DOP) / STD Pack: 8.000 pcs</p> <p>C11700030 - ETO - Radiation</p>	
<p>“T” connector 1 female for tube Ø 6.8 mm + 1 male for tube Ø 6.8 mm heparine Ø 4.1 mm Material: Soft PVC (*NO-DOP) / STD Pack: 8.000 pcs</p> <p>C11710030 - ETO - Radiation</p>	
<p>“T” connector 1 female for tube Ø 6.8 mm + 1 male for tube Ø 6.8 mm heparine Ø 3.7 mm Material: Soft PVC (*NO-DOP) / STD Pack: 8.000 pcs</p> <p>C11740030 - ETO - Radiation</p>	
<p>Elbow connector 1 for tube Ø 6.8 mm + 1 for tube Ø 5.5 mm Material: Soft PVC (*NO-DOP) / STD Pack: 10.000 pcs</p> <p>C16100030 - ETO - Radiation</p>	
<p>Elbow connector 1 for tube Ø 6.8 mm + 1 for tube Ø 4.1 mm Material: Soft PVC (*NO-DOP) / STD Pack: 10.000 pcs</p> <p>C16110030 - ETO - Radiation</p>	



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5.4 - Suction and Hansen connectors






<p>Suction connector set "CH 25" for tube \varnothing 8.5 mm Material: Soft PVC (*NO-DOP) / STD Pack: 2.000 pcs C12320793 - ETO - Radiation (Blue)</p>	
<p>Suction connector set "CH 30" for tube \varnothing 10.0 mm Material: Soft PVC (*NO-DOP) / STD Pack: 2.000 pcs S1010xxxxx - ETO - Radiation (Blue)</p>	
<p>Suction connector set "CH 25" for tube \varnothing 8.0 mm Material: Soft PVC (*NO-DOP) / STD Pack: 2.000 pcs S1011xxxxx - ETO - Radiation (Blue)</p>	
<p>Suction connector set "CH 25" for tube \varnothing 6.8mm Material: Soft PVC (*NO-DOP) / STD Pack: 3.000 pcs S1012xxxxx - ETO - Radiation (Blue)</p>	

Dimension: "mm" • All components in Soft PVC are available in NO-DOP too



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5.4 - Suction and Hansen connectors

<p>Pvc funnel connector "CH 6" for tube Ø 2.0 mm Material: Soft PVC / STD Pack: 5.000 pcs S1030xxxxx - ETO (Light Green)</p>	
<p>Pvc funnel connector "CH 8" for tube Ø 2.7 mm Material: Soft PVC / STD Pack: 5.000 pcs S1031xxxxx - ETO (Light Blue)</p>	
<p>Pvc funnel connector "CH 10" for tube Ø 3.4 mm Material: Soft PVC / STD Pack: 5.000 pcs S1032xxxxx - ETO (Black)</p>	
<p>Pvc funnel connector "CH 12" for tube Ø 4.0 mm Material: Soft PVC / STD Pack: 5.000 pcs S1033xxxxx - ETO (White)</p>	
<p>Pvc funnel connector "CH 14" for tube Ø 4.7 mm Material: Soft PVC / STD Pack: 5.000 pcs S1034xxxxx - ETO (Green)</p>	



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5.4 - Suction and Hansen connectors

<p>Pvc funnel connector "CH 16" for tube \varnothing 5.4 mm Material: Soft PVC / STD Pack: 5.000 pcs S1035xxxx - ETO (Orange)</p>	
<p>Pvc funnel connector "CH 18" for tube \varnothing 6.0 mm Material: Soft PVC / STD Pack: 5.000 pcs S1036xxxx - ETO (Red)</p>	
<p>Pvc funnel connector "CH 20" for tube \varnothing 6.7 mm Material: Soft PVC / STD Pack: 5.000 pcs S1037xxxx - ETO (Yellow)</p>	
<p>Pvc funnel connector "CH 22" for tube \varnothing 7.4 mm Material: Soft PVC / STD Pack: 5.000 pcs S1038xxxx - ETO (Pink)</p>	

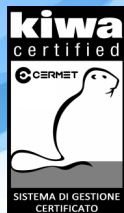


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5.5 - Catheter connectors

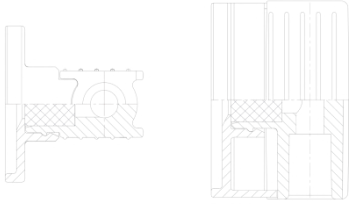
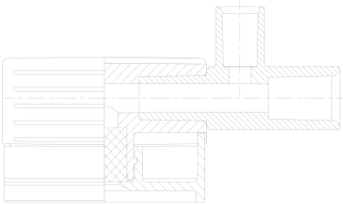
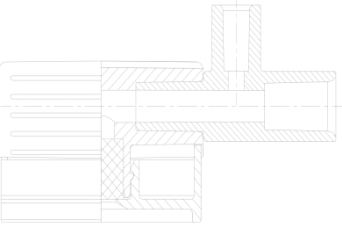
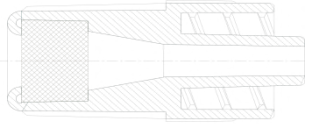
<p>Catheter cone for tube Ø 8.0 mm Material: ABS / STD Pack: 4.000 pcs 7104130300 - ETO - Radiation (Neutral)</p>	
<p>Catheter cone for tube Ø 9.8 mm Material: ABS / STD Pack: 4.000 pcs 7104120300 - ETO - Radiation (Neutral)</p>	
<p>Catheter cone w/drawing point for tube Ø 9.8 mm Material: ABS - Polyisoprene / STD Pack: 4.000 pcs 9806220102 - ETO (Neutral)</p>	
<p>Catheter cone w/drawing point for tube Ø 8.0 mm Material: ABS - Polyisoprene / STD Pack: 4.000 pcs 9806230102 - ETO (Neutral)</p>	

Dimension: "mm"



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6. Injections sites

<p>Injection site with finger protection for tube \varnothing 6.8 mm Material: PP - Polyisoprene - (latex free) - Rigid PVC STD Pack: 2.500 pcs</p> <p>A00209392 - ETO (Red) A00209393 - ETO (Blue) A00209382 - Radiation (Red) A00209383 - Radiation (Blue)</p>	
<p>Injection site with finger protection for tube \varnothing 6.8 mm + service line \varnothing 5.5 mm Material: PP - Polyisoprene - (latex free) - Rigid PVC Soft PVC (*NO-DOP) / STD Pack: 2.000 pcs</p> <p>A00409392 - ETO (Red) A00409393 - ETO (Blue) A00409382 - Radiation (Red) A00409383 - Radiation (Blue)</p>	
<p>Injection site with finger protection for tube \varnothing 6.8 mm + service line \varnothing 4.1 mm Material: PP - Polyisoprene - (latex free) - Rigid PVC Soft PVC (*NO-DOP) / STD Pack: 2.000 pcs</p> <p>A00419392 - ETO (Red) A00419393 - ETO (Blue) A00419382 - Radiation (Red) A00419383 - Radiation (Blue)</p>	
<p>Injection site with male luer lock Material: ABS - Polyisoprene - (latex free) / STD Pack: 20.000 pcs A03009390 - ETO - Radiation (Neutral)</p>	



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8. Piercing devices





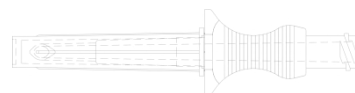
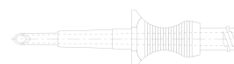
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8.1 - Piercing devices

1 way spike female luer lock
Material: ABS / STD Pack: 4.000 pcs

C13404061 - ETO - Radiation
C13404121 - ETO - Radiation
C13404161 - ETO - Radiation

1 way spike female luer lock with vented cap
Material: ABS / LDPE Pack: 4.000 pcs
A01709970 - ETO - Radiation
A01709990 - ETO - Radiation



Dimension: "mm"



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8.1 - Pasteur drip chamber

Pasteur drip chamber
for tube \varnothing 9.8 mm
Material: Soft PVC - Rigid PVC - PE / STD Pack: 800 pcs
980450002 - ETO

Dimension: "mm" • All components in Soft PVC are available in NO-DOP too



