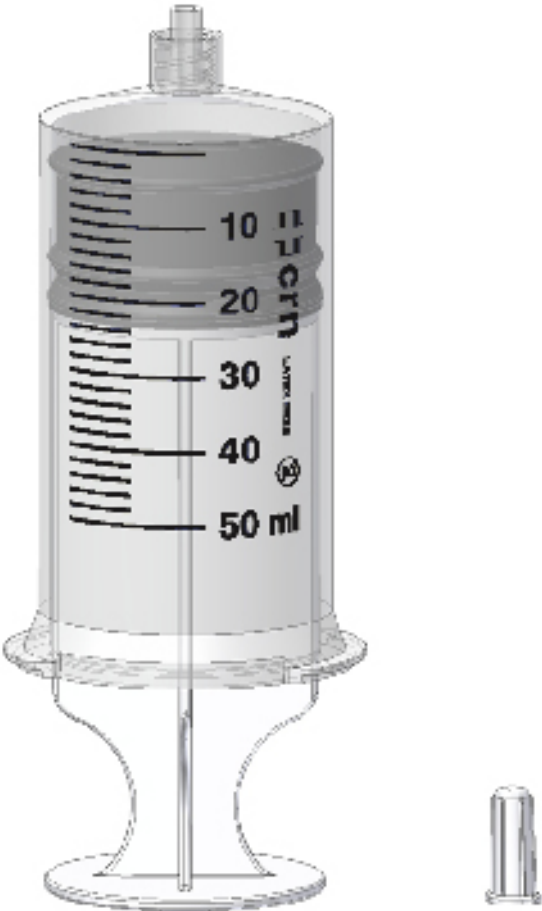



RÉSERVOIR PARTS	CLASSIFICATION
	<p>The disposable syringe with needle pertains to IIa class for medical devices, conforming to Rule 6 Enclosure IX directive 93/42 CEE of the Council June 14, 1993.</p> <p>CE Mark: 0123</p>
	<p>MANUFACTURER</p>
	<p>Pentaferte S.p.A. Statale 262 Località Nocella 64012 Campoli (TE) Phone: +39.0861.560201 Fax: +39.0861.560202</p>
	<p>CND CODE</p>
<p>A020102020102</p>	

WARNING
<ul style="list-style-type: none"> • The CRN® CRONO® reservoirs have been designed to be used exclusively with CRONO® model pumps. • The use of CRN® CRONO® reservoirs with other pumps, not of the Crono series, can cause damage to the pump and injury to the patient. • CANÈ S.p.A. declines all responsibility if: <ul style="list-style-type: none"> - CRN® CRONO® reservoirs are used with other devices - CRONO® model pumps are used with reservoirs other than original CRN® CRONO® reservoirs

COMPONENT (Drawing's code)	FEATURES (Standard's reference)	MATERIAL (Data sheet)
50ml rod (CRN/22)	Flange cylinder/flange distance: min.10mm (ISO 7886-2) The head is threaded to unscrew the rubber piston	Matt Polypropylene medical degree HF136MO (Annex II)
50 ml cylinder (CRN/21-A)	Utilizable capacity: min. 55 ml Luer Lock cone (ISO 594/1 and 594/2)	Transparent polypropylene medical degree RF825MO (Annex III)
	Scale Graduation space:2ml (ISO 7886-1) Scale numeration: every 10ml (ISO 7886-1) Capacity output tolerance beyond 25ml: +/-4% (ISO 8537)	Black ink
	Lubrication: maximum quantity 0,25 mg/cm2 of internal surface (ISO 7886-1)	Silicone oil + isooctane diluent (Annex IV)
50ml piston (CRN/21-B)	Black colour; two hold rings Lubricant: silicone viscosity 1000 Internal screw threading with head/rod	Latex Free rubber complying to U.F. (Annex V)
Luer-lock cap (CRN/23)	Cap: cone Luer 6% (ISO 594/1) to inserting on Luer Lock cone	Polypropylene medical degree HF136MO
Assembled syringe	Hold while compressing: min.2300 kPa (ISO 7886-1) Dead space: max. 0,17ml (ISO 7886-1)	-----

COMPONENT (Drawing's code)	FEATURES (Standard's reference)	MATERIAL (Data sheet)
Packing	Paper: 80 g/m2 Stamping: Product description, Lot Nr., Expiring date	Medical degree paper Film (Annex VI)
	Film: 270 µm thickness Type of opening/blister: PEEL	APET/PE
Box	Number of pieces per dinking die: 60 External dim.: (mm): 360 x 370 x 240 Stamping: Product description, Lot Nr., Expiring date,	Corrugated cardboard with white kraft external cover (Annex VII)
Sterilization	Mixture: Ethylene Oxide 10%+CO2 90% Autoclaves capacity: 24 m3 and 40 m3 Cycle validation notified by external SINAL accredited Laboratory, according to EN 550 standard "Medical devices' sterilization - Routine's validation and control of ethylene oxyde sterilization"	

EXPIRY DATE (SHELF LIFE)	STORAGE TEMPERATURE
5 years from the manufacture date	-10°C to 40°C

PRO-FILL CRN PARTS	CLASSIFICATION
	<p>The disposable needle for aspiration PRO-FILL-CRN pertains to Is class for medical devices, conforming to Rule 6 Enclosure IX directive 93/42 CEE of the Council june 14, 1993.</p> <p align="center">CE Mark: 0123</p>
	MANUFACTURER
	<p>MULTIMEDICAL S.r.l. Via Guido Rossa, 71 Zona Industriale Gerbolina 46019 Viadana (MN) - Italy Tel: +39.0375.785882 Fax: +39.0375.785885</p>
	CND CODE
	A0701
	GMDN CODE
16774	

COMPONENT (Drawing's code)	FEATURES (Standard's reference)	MATERIAL (Data sheet)
Needle 14 G x 11/2" on side	Barrel: cone Luer 6% (ISO 594/1) Standard coloring ISO	Transparent polypropylene medical degree + coloured master medical degree
	Needle cover	Transparent polypropylene medical degree
	Labyrinthine cap: cone Luer 6% (ISO 594/1)	Transparent polypropylene medical degree
	Cannula: Triple sharpening with primary angle 16° +/- 2° (ISO 7864) External diameter and internal diameter complying to ISO 9626 standard Length complying to ISO 7864 standard Anticoring treatment Cleaning: electrocleaning + ultrasounds	Stainless steel AISI 304
	Glue	Epoxy resin
	Lubricating	Silicone Polydymetilsiloxane (complying to ISO 7864 and FDA standard)

Final inspection at the factory			
Item	AQL	Item	AQL
Hub - Hub color	0.1%	Penetration	1%
Conical fitting Gauging test	1%	Cleanliness of cannula	1%
External thread	1%	Intactness of cannula point	1%
Needle tube length front	1%	Cleanliness of sheath	1%
Bond between hub and needle tube	1%	Intactness of sheath	1%