


SYRINGE 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>
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	<p>CND CODE</p>
<p>A020102020101</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



CRN® CRONO® SYRINGE 10 ml SPECIFICATIONS

Rev. 8 of 01.12.2014

COMPONENT (Drawing's code)	FEATURES (Standard's reference)	MATERIAL (Data sheet)
10ml rod (CRN/01b/B)	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)
10ml cylinder (CRN/01a/D)	Utilizable capacity: min.11 ml Luer Lock cone (ISO 594/1 and 594/2)	Transparent polypropylene medical degree RF825MO (Annex III)
	Scale Graduation space: 1ml (ISO 7886-1) Scale numeration: every 5ml (ISO 7886-1) Capacity output tolerance beyond 5ml: +/-4% (ISO 8537)	Black ink
	Lubrication: maximum quantity 0,25 mg/cm2 of internal surface (ISO 7886-1)	Silicone oil + isoctane diluent (Annex IV)
10ml piston (CRN/05/C)	Black colour; two hold rings Lubricant: silicone viscosity 1000 Internal screw threading with head/rod	Latex and 2MBT Free rubber
Needle 19 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
	Cannula: Triple sharpening with primary angle 11°+/-2° (ISO 7864) External diameter and internal diameter complying to ISO 9626 standard Length complying to ISO 7864 standard Cleaning: electrocleaning + ultrasounds	Stainless steel AISI 304 Epoxy resin Silicone Polydymetilsiloxane (complying to ISO 7864 and FDA standard)
Luer-lock cap (CRN/25)	Blue cap: cone Luer 6% (ISO 594/1) to inserting on Luer Lock cone	Polypropylene medical degree + coloured master medical degree
Assembled syringe (CRN/02/B)	Hold while compressing: min. 300 kPa (ISO 7886-1) Dead space: max. 0,10ml (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
	Film: 90 µm thickness Type of opening/blister: PEEL	PP/PE
Box	Number of pieces per dinking die: 80 External dim.: (mm.) 382 x 232 x 183 Stamping: Product description, Lot Nr., Expiring date	Corrugated cardboard with white kraft external cover
Master	Number of dinking die per master: 4 (total 320 pcs) External dim.: (mm.) 394 x 394 x 482 Stamping: Product description, Lot Nr., Expiring date, Sterilization's cycle Nr.	Two waves microtriple corrugated cardboard with white kraft external cover
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

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