

Article code	7981834
Article name acc. DoC	Freka® Trelumina, ENFit
Class acc. Directive 93/42/EEC	IIa

Article code	Article name	Material
9000784	Freka Connect ENFit / ProNeo syringe	●Syringe Barrel: PP (Polypropylene) ●Syringe Plunger: PP (Polypropylene) ●Syringe Gasket - Isoprene Rubber ●Lubricant - medical silicone oil ●Print - PPE (Polyphenylenether) Ink Series
C11515	Solvent	●MEK (Methylethylketone)
C11553	Solvent	●CHN (Cyclohexanone)
C21873	Tube connector 3-lumen tube	●TPU (thermoplastic Polyurethane) ●Resin ester polymer (carrier material)
C21877	Tube tip	●PUR (Polyurethane) with 10% BaSO₄ ●Lubricant: Amide wax
C22024	Connecting funnel	● TPU (thermoplastic Polyurethane) ●Resin ester polymer (carrier material)
C22572	Lubricant	●PDMS (Polydimethylsiloxane)
C22704	Fixation tape	●polyester fleece non-woven ●polyacrylate adhesive ●siliconized paper liner
	Back check valve	●Solvent: TEF (Tetrahydrofuran) ●Check Valve: MABS (Methymethacrylate Acrylonitrile Butadiene Styrene), 2% Masterbatch ●Valve membrane: Silicone
C30823	ENFit female cap	●HDPE (high density Polyethylene) ●colourant violet
C30824	Strap for ENFit cap, ring-Ø 10.5 mm	●LDPE (low density polyethylene), transparent
C30834	ENFit female oral / LL	●POM (Polyoxymethylene)
C30841	ENFit male 8 FR	●PET (Polyethyleneterephthalate) (Copolyester) ●colourant violet
	Tube 1.85 x 0.55 mm	●PUR (Polyurethane) and PUR + 60% BaSO ₄ (one x-ray contrast strip)
C30980	Tube 1.85 x 0.55 mm	●PUR (Polyurethane) with 20% BaSO ₄ + Colourant (white)
C30988	Tube 3.0 x 0.7 x 109 mm	●PUR (Polyurethane)
C31527	Printing ink, black	●Stamping ink
C31534	Tube printing ink	●Butanone ●Solvent Black 29 ●Ethanol ●Cellulose Nitrate ●Isopropyl Acetate ●2-Naphtole
C31535	Tube printing ink thinner	●Butanone ●Acetone
J1040027		
C22174	MCT-oil and vials	●Oil: medium-chain triglycerides - caproic acid 0-2%, caprylic acid 50-65%, capric acid 35-

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		45%, lauric acid 0-3% ●Vials: LDPE (low density polyethylene)
C22636	Seal bags 145 x 60 mm	●PES (Polyester) ●ALU (Aluminium) foil ●PE (Polyethylene)
J1040108		
C11515	Solvent	●MEK (Methylethylketone)
C11553	Solvent	●CHN (Cyclohexanone)
	Connecting funnel	●TPU (thermoplastic Polyurethane) ●Preparation of a colour agent in a universal carrier ●Lubricant (Amid wax) ●TPU-(thermoplastic Polyurethane)-based anti-blocking agent
C22503	Ethanol absolute	●Ethanol absolute, REACH No. 01-2119457610-43, EC-No. 200-578-6, Index-No. 603-002-00-5
C22572	Lubricant	●PDMS (Polydimethylsiloxane)
C30975	Tube 3.25 x 0.9 x 350 mm	●PVC (Polyvinylchloride), plasticizer DEHP, Colourant
J1040180		
C10569	Tube plug	●TPU (Polyether-based Polyurethane) + 20% BaSO ₄ ●TPU (Thermoplastic Polyurethane) ●Resin ester polymer (carrier material)
C11515	Solvent	●MEK (Methylethylketone)
C11553	Solvent	●CHN (Cyclohexanone)
C21870	Upper part	●TPU (thermoplastic Polyurethane) ●Resin ester polymer (carrier material) ●TPU-(thermoplastic Polyurethane)-based anti-blocking agent
C30072	Hose injection square	●TPU (thermoplastic Polyurethane) ●Resin ester polymer (carrier material)
C30073	Hose injection Housing	●TPU (thermoplastic Polyurethane) ●Resin ester polymer (carrier material)
	transition olive to 3-lumen tubing	●TPU (thermoplastic Polyurethane) + 20% BaSO ₄ ●Resin ester polymer (carrier material)
C30969	Tube 3.5 x 0.58 mm	●PUR (Polyurethane) and PUR (Polyurethane) with 60% BaSO ₄ + Colourant (white)
C30983	Tube 3-Lumen d1=4.13mm, d2=1.4mm, d3=1.2mm, OD 5.33mm, length 945mm	●PUR (Polyurethane) and PUR (Polyurethane) with 60 % BaSO ₄
C31534	Tube printing ink	●Butanone ●Solvent Black 29 ●Ethanol ●Cellulose Nitrate ●Isopropyle Acetate ●2-Naphtole
C31535	Tube printing ink thinner	●Butanone ●Acetone
J1040256		
C22622	Mandrin 1.14 x 1477 mm	●1. spiral wire, coated: Stainless steel similar to 1.4310, Polymer blend (PTFE

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		(Polytetrafluoroethylene), PES (Polyethersulfone), PAI (Polyamide-Imide) ●2. inner wire: Stainless steel 1.4310 ●3. solder joint
C22638	Ethanol 70%	●Ethyl alcohol 70%
●THF (Tetrahydrofuran), also 1,4-Epoxy butane	Guide wire grip ENFit, 1.14 mm	●MABS (Methylmethacrylate Acrylnitrile Butadiene Styrene) ●Resin ester polymer (carrier material)
C30819	Glue	●superglue based on Alkoxyethyl cyanoacrylate
Packaging		
C11517	Adhesive tape paper	●gummed paper tapes Polyeste filament yarn for strengthening
C11806	ETIKETT EDV	●N/A
C12055	Tamper-evident safety seal	●PP (Polypropylene) -Film Transparent- 60 µm Top Coat ●Adhesive: Permanent -958 ●Base: Glassine paper B 700-476
C12447	Label sticker 140 x 175 mm	●Paper and Adhesive (acrylate dispersion)
C12724	Instructions leaflet	●Paper
C31045	Stretch film	●LLDPE (linear low density polyethylene)
C31046	Stretch film foil plate	●LDPE (low density polyethylene)
C31086	Cardboard 324 x 279 x 188 mm	●Corrugated cardboard
C31351	Compound foil 30/70 µm	●PA (Polyamide)/PE (Polyethylene)
C31526	Thinner for printing ink	●1-Methoxy-2-Propanol (2-Methoxymethylethoxy) propanol
C51027	Folded carton box, brown, 260x250x35 mm	●Material: Testliner ●Wave: E
C61300	Automat reel without print	●Paper
Sterilization		
C11525	Indicator tape for EO sterilization	●Process indicator tape for Ethylene Oxide (EO) sterilization
C31500	Sterilization gas, Poland	●100% Ethylene oxide, liquefied grade one (GAZ 4-134) ●alternative: > 99.9% Ethylene oxide