

Article code	M90800349
Article name acc. DoC	Freka® PEG Pro Set FR 16
Class acc. MDR 2017/745	IIb

Article code	Article name	Material
C11515	Solvent	●MEK (Methylethylketone)
C11553	Solvent	●CHN (Cyclohexanone)
C21832	Spool and thread	●MABS (Methylmethacrylate Acrylonitrile Butadiene Styrene), Colourant (blue) ●PA 6 / PA 6.6
C21935	Tube clamp	●POM (Polyoxymethylene) or Acetal-Copolymer, base resin + additives ●Resin ester polymer (carrier material) + pigment dispersion
C30473	Insert Aid	●PP (Polypropylene) ●blue colourant; Resin ester polymer (carrier material) + pigment dispersion
C30474	Tray	●PETG (Polyethyleneterephthalate Glycol) foil, blue ●Amorphous polyester, copolyester
C31526	Thinner for printing ink	●1-Methoxy-2-Propanol (2-Methoxymethylethoxy) propanol
C31527	Printing ink, black	●Stamping ink
C31586	PenBlade-11P Safety Scalpel	●blade: stainless steel ●body: ABS (Acrylonitrile Butadiene Styrene) resin, colourant: orange + white ●spring: SUS 304 Polymer
J1040239		
C30471	ENFit connector FR 16	●PBT (Polybutyleneterephthalate) ●dark blue PE-LLD (Polyethylene - linear low density) with organic and inorganic color pigments
C30823	ENFit female cap	●HDPE (high density Polyethylene) ●colourant violet
C30897	Strap for ENFit male connector	●LDPE (Low density polyethylene)
J1040241		
C30451	Retention plate clamp FR 16	●POM (Polyoxymethylene-Copolymer) or Acetal-Copolymer (base resin ≥ 99%, additives < 1%); ●dark blue PE-LLD (Polyethylene - linear low density) with organic and inorganic color pigments

Article code	Article name	Material
C30472	Retention plate FR 16	●Polydimethylesiloxane (Silicone elastomer) containing vinyl groups, with Platinum catalyst and inhibitors ●Bariumsulphate ●Polydimethylsiloxane containing Vinyl-groups
J1040248		
C11515	Solvent	●MEK (Methylethylketone)
C22558	Glue	●ECA (Ethyl-2-Cyanoacrylate); Hydrochinon (0.01- < 0.1% w/w)
C22573	Lubricant	●Siloxane
C30463	Lower Body	●ABS (Acrylonitrile-Butadiene-Styrene) ●colourant white, Carrier: ABS (Acrylonitrile-Butadiene-Styrene) with inorganic color pigments
C30464	Upper Body	●ABS (Acrylonitrile-Butadiene-Styrene) ● colourant white, Carrier: ABS (acrylonitrile-butadiene-styrene) with inorganic color pigments
C30465	Safety Clip	●ABS (Acrylonitrile-Butadiene-Styrene)
C30466	Needle Button	●ABS (Acrylonitrile-Butadiene-Styrene) ●colourant blue, Universal masterbatch Carrier: resin ester - polymer
C30467	Unlock Button	●ABS (Acrylonitrile-Butadiene-Styrene) ●colourant grey, Universal masterbatch Carrier: resin ester - polymer
C30468	Duckbill valve	●VMQ Silicone
C30469	Trocar	●Stainless steel 1.4301
C30490	Capillary 8/80, length 109 mm	●Fluorinated Ethylene-Propylene (FEP); ●Stripes: Pantone 542 blue; ●X-ray contrast agent: 24% BaSO₄ (pre-mixed in main material)
C31757	PTFE (Polytetrafluoroethylene) Etching Agent	●Etching Agent for PTFE
J1040251		
C22559	Glue	●ECA (Ethyl-2-Cyanoacrylate); Hydrochinon (0.01- < 0.1% w/w)
C22691	Fixation loop, OD 0.4 ± 0.01mm	●Core: PA 6.6 (Polyamide 6.6) ●Coating: PA 6 (Polyamide 6)
C30461	Tube Cone FR 16	●TPU (thermoplastic Polyurethane), Polyester-based ●colourant white Carrier material: resin-ester polymer with pigment additive
J1040268		

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C21854	Fixation ring	●Thermoplastic Elastomer (TPE) ●Resin ester polymer (carrier material)
C21857	Fixation aid PEG	●PBT (Polybutylenterephthalate) ●Resin ester polymer (carrier material) + pigment dispersion
C30483	Connector screw FR 16	●PBT (Polybutyleneterephthalate); ●dark blue PE-LLD (Polyethylene - linear low density) with organic and inorganic color pigments
J1040273		
C22124	Ring for gastric retention disc	●PEEK (Polyetheretherketone)
C22503	Ethanol absolute	●Ethanol absolute
C22559	Glue	●ECA (Ethyl-2-Cyanoacrylate); Hydrochinon (0.01- < 0.1% w/w)
C30485	Inner Retention Plate LSR FR 16	●PDMS (Polydimethylesiloxane) (Silicone elastomer) containing vinyl groups, with Platinum catalyst and inhibitors ●Bariumsulphate ●PDMS (Polydimethylsiloxane) containing Vinyl-groups
C31531	Tube printing ink	●Ketone based colourant (cyclohexanone (5-10%), butanone (70-80%))
C31532	Tube printing ink thinner	●Ketone based additive (Butanone = Methyl ethyl ketone, 90-100%)
C31650	Tube overmould FR 16	●TPU (thermoplastic Polyurethane), aromatic-based
C60935	PUR (Polyurethane) tube FR 16 (4.05 x 5.33 mm), natural	●PUR (Polyurethane) tube FR 16, natural 1 RKS (X-ray-stripe): PUR (Polyurethane) with 60% BaSO₄ (X-ray contrast stripe - colour white)
Packaging		
	Adhesive tape paper	●gummed paper tapes - Polyeste filament yarn for strengthening
	ETIKETT EDV	●N/A
	Tamper-evident safety seal	●PP (Polypropylene) -Film Transparent- 60 µm Top Coat ●Adhesive: Permanent -958 ●Base: Glassine paper B 700-476
	Patient label 76x47 mm	●Paper and adhesive (acrylat dispersion)
	Label sticker 140 x 175 mm	●Paper and Adhesive (acrylate dispersion)
	IFU PEG PRO	●Paper
	Patient Information PEG PRO	●Paper 115g/80g
	Implant Card PEG PRO	●Carton 135-215 g/qm
	Natron Paper 1000 x 750 mm	●Color brown
	Stretch film	●LLDPE (linear low density polyethylene)

Article code	Article name	Material
	Stretch film foil plate	●LDPE (low density polyethylene)
	Cardboard 324 x 279 x 188 mm	●Corrugated cardboard
	Compound foil 30/70 µm	●PA (Polyamide)/PE (Polyethylene)
	Folded carton box, brown, 280x180x45 mm	● Material: Testliner ● Wave: E
	Automat reel without print	●Paper
Sterilization		
	Indicator tape for EO sterilization	●Process indicator tape for Ethylene Oxide (EO) sterilization
	Sterilization gas	●Ethylene oxide