

Article code	M90800373
Article name acc. DoC	Freka® Intestinal Tube FR 9 for Freka PEG FR 16
Class acc. MDR 2017/745	IIb

Article code	Article name	Material
C11515	Solvent	●MEK (Methylethylketone)
C11553	Solvent	●CHN (Cyclohexanone)
C21898	End piece (flexible tip)	●PUR (Polyurethane)
C22559	Glue	●ECA (Ethyl-2-Cyanoacrylate); Hydrochinon
C22563	Mini tube 2.0 x 0.18 x 11.5 mm	●Stainless steel 1.4541
C22572	Lubricant	●PDMS (Polydimethylsiloxane)
C30841	ENFit male 8 FR	●PET (Polyethyleneterephthalate) (Copolyester) ●colourant violet
J1040132		
C21811	Connecting funnel	●TPU (thermoplastic Polyurethane), Polyether-based ●Carrier: resin-ester polymer with pigment dispersion ●Lubricant (Amid wax)
C22559	Glue	●ECA (Ethyl-2-Cyanoacrylate); Hydrochinon
C30807	ENLock Y-piece	●PBT (Polybutylenterephthalate) ●Resin ester polymer (carrier material) + pigment dispersion
C30810	Sealed housing for click-adaptor	●PBT (Polybutylenterephthalate) ●Resin ester polymer (carrier material) + pigment additive
J1040133		
C21831	Interior fixation screw	●PBT (Polybutylenterephthalate) ●Resin ester polymer (carrier material) + pigment dispersion
C21849	Adaptor exterior part	●POM (Polyoxymethylene) or Acetal-Copolymer ●Carrier: resin-ester polymer with pigment dispersion
C21858	Fixation ring	●TPE (Thermoplastic Elastomer) ● color: white
C21938	Adaptor interior part	●PBT (Polybutylenterephthalate) ●Carrier: resin-ester polymer with pigment dispersion
C22054	O-ring	●Siloxane MVQ-Silicone (Methyl-Vinyl-Silicone rubber)
C22559	Glue	●ECA (Ethyl-2-Cyanoacrylate); Hydrochinon
C30806	ENLock removableClick Screw	●PBT (Polybutylenterephthalate) ●Resin ester polymer (carrier material) + pigment dispersion
J1040199		
C22568	Mini tube 2.2 x 0.18 x 11.5 mm	●Stainless steel
C22596	Glue	●Epoxy Resin (Reaction mass of trientine and trientine, mono- and di-propoxylated)
C22597	Glue hardener	●Modified Polyamine (2,2'-[(1-methylethyldiene) bis(4,1-phenyleneoxymethylene)] bisoxirane, diethyl phthalate
C30823	ENFit female cap	●HDPE (high density Polyethylene) ●colourant violet
C30895	ENFit male - PEG connector	●PBT (Polybutylenterephthalate)

Article code	Article name	Material
		●Resin ester polymer (carrier material)
C30897	Strap for ENFit male connector	●LDPE (Low density polyethylene)
J1040268		
C21854	Fixation ring	●Thermoplastic Elastomer (TPE) ●Resin ester polymer (carrier material)
C21857	Fixation aid PEG	●PBT (Polybutyleneterephthalate) ●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
J1040278		
C22559	Glue	●ECA (Ethyl-2-Cyanoacrylate); Hydrochinon
C30810	Sealed housing for click-adaptor	●PBT (Polybutyleneterephthalate) ●Resin ester polymer (carrier material) + pigment additive
C30823	ENFit female cap	●HDPE (high density Polyethylene) ●colourant violet
C30897	Strap for ENFit male connector	●LDPE (Low density polyethylene)
C31700	ENFit Removable Y FR 15 for Clickadaptor	●PBT (Polybutylene-terephthalate) ●Masterbatch - colourant – white, Carrier: resin-ester polymer with pigment dispersion
C31704	Screw Collar ENFit	●PBT (Polybutylene-terephthalate) ●Masterbatch - colourant – white, Carrier: resin-ester polymer with pigment dispersion
J1040305		
C22638	Ethanol 70%	●Ethyl alcohol 70%
C30819	Glue	●superglue based on Alkoxyethyl cyanoacrylate
C31653	ENFit guide wire grip	●MABS (Methylmethacrylat-Acrylnitril-Butadien-Styrol) ●Masterbatch - colourant – white, Carrier: resin-ester polymer with pigment dispersion
C31705	Mandrin	●Wire: Stainless Steel ●Coating: PTFE, green, Coating thickness: 2-7 µm
J1060330		
C30979	Tube 1.9 x 0.51	●PUR (Polyurethane) and PUR + 60% BaSO4 (one x-ray contrast strip)
C31534	Tube printing ink	●Butanone ●Solvent Black 29 ●Ethanol ●Cellulose Nitrate ●Isopropyl Acetate ●2-Naphtole
C31535	Tube printing ink thinner	●Butanone ●Acetone
Packaging		
	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

Article code	Article name	Material
	Label Sticker 50 x 22 mm	●Paper and Adhesive
	Label sticker 140 x 175 mm	●Paper and Adhesive (acrylate dispersion)
	Patient information	●Paper Matt 80g/m2 + cover maxi satin 115g/m2
	Instruction for use	●Paper Matt 80g/m2 + cover maxi satin 115g/m2
	Stretch film	●LLDPE (linear low density polyethylene)
	Stretch film foil plate	●LDPE (low density polyethylene)
	Cardboard 290 x 187 x 205 mm	●Corrugated cardboard, color brown
	Compound foil 30/70 µm	●PA (Polyamide)/PE (Polyethylene)
	Black ink	●Printing ink
	Folded carton box, brown, 270x150x30 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