

Article code	7751386
Article name acc. DoC	Freka® Belly Button, Comfort Kit, FR 16 2.5 cm, ENFit
Class acc. Directive 93/42/EEC	IIb

Article code	Article name	Material
Material 17	Shaft	●LSR (Liquid Silicone Rubber)
Material 18	Button Body	●LSR (Liquid Silicone Rubber)
Material 19	Duckbill Valve	●LSR (Liquid Silicone Rubber)
Material 20	Balloon	●LSR (Liquid Silicone Rubber)
Material 21	Connector Ring	●plastic
Material 22	Check Valve	●PC (polycarbonate), Silicone, UV adhesive, stainless steel, colourant
Material 24	Stylus	●Fresenius Stylus: ABS (Acrylonitrile Butadiene Styrene) + colourant ●Degania Stylus (FR 12-14): PC (Polycarbonate) + colourant
Material 25	Syringe 5 ml (FR 12-18) or 10 ml (FR 20+ 24)	Barrel: PP (Polypropylene), latex-free Plunger: PP (Polypropylene), latex-free elastomer Lubricant: Silicone oil
Material 26	Gauze Pad	●30% Polyester, 70% Viscose; 34 g/m ² ; unfolded 200 x 200 mm
Material 27	Lubricant jelly	●CE conform water soluble liquid jelly, sterile; 5g sachet 100 x 35 x 5 mm, contains sodium hydroxide
Material 41	Patient sticker 4 pcs. each	●autoadhesive white paper
9000786	Freka Connect ENFit	
Material 112	Syringe barrel	●PP (Polypropylene)
Material 113	Syringe piston	●PP (Polypropylene) + colourant lilac
Material 114	Syringe gasket	●IR (Isoprene Rubber) (Latex Free)
Material 115	Lubricant	●Medical Silicone Oil
Material 116	Print	composition in %: ●Pigment 1.1 to 60 ●Aromatic Hydrocarbon solvents 10 to 80 ●Synthetic resin 20 to 40 ●Adjuvant 1 to 10
7989911	Freka Seldinger Wire	
C22527	Guide wire cartridge / dispenser	●MDPE (medium density polyethylene), mixture of HDPE (high density polyethylene) and LDPE (low density polyethylene)
C22539	Guide wire 1.14 x 800 mm	●Stainless steel Teflon-coating blend of PTFE (Polytetrafluoroethylene), PES (Polyethersulfone), PAI (Polyamide-Imide), thickness 4-5 µm
C22572	Lubricant	●PDMS (Polydimethylsiloxane)
C31525	Printing ink, blue	●Mixture (colourant and thinners)

Article code	Article name	Material
C31526	Thinner for printing ink	●1-Methoxy-2-Propanol (2-Methoxymethylethoxy) propanol
7981397	Freka Extensions Set # 1	
Material 2	ENFit connector	●ABS (Acrylonitrile Butadiene Styrene), violet
Material 4	Pinch Clamp	●POM (Polyoxymethylene)
Material 6	Button connector straight or right angled	●ABS (Acrylonitrile-Butadiene-Styrene), white
Material 7	Tube 4.1 x 3.1 x 300 x 15 mm	●PUR (polyurethane), transparent
7981398	Freka Extensions Set # 2	
Material 2	ENFit connector	●ABS (Acrylonitrile Butadiene Styrene), violet
Material 4	Pinch Clamp	●POM (Polyoxymethylene)
Material 6	Button connector straight or right angled	●ABS (Acrylonitrile-Butadiene-Styrene), white
Material 7	Tube 4.1 x 3.1 x 300 x 15 mm	●PUR (polyurethane), transparent
Packaging		
Material 36	Hard blister primary packaging 232 x 100 mm	●PET (Polyethylenterephthalate)
Material 39	Secondary packaging: Carton box 270 x 170 x 55 mm	●carton
Material 40	Tertiary packaging: Carton box 260 x 285 x 288 mm	●carton
Material 42	Labels	●Paper
Material 43	IFU 257 x 165 mm	●paper recycled 80 g/sqm
Sterilization		
	Indicator tape for EO sterilization	●Process indicator tape for Ethylene Oxide (EO) sterilization
	Sterilization gas	●100% Ethylene oxide