

Article code	7751956 (M44310002)
Article name acc. DoC	Amika Bag, ENFit
Class acc. MDR 2017/745	Ila

Article code	Article name	Material
C10419	Amika clamp	●PC (Polycarbonate) based on Bisphenole A ●Colorbatch lilac
C11503	Solvent	●THF (Tetrahydrofuran), also 1,4-Epoxy butane
C11504	Solvent / Lubricant	●Isopropyle alcohol
C11511	Lubricant	●Aminofunctional Siloxane
C11553	Solvent	●CHN (Cyclohexanone)
C30830	ENFit Stopcock 5.0 mm (closed)	●housing: Copolyester (BPA-free) ●handle: HDPE (high density polyethylene) with colourant ●Silicone PDMS (Polydimethylsiloxane)
C30931	Tube 3 x 5 mm	●PVC (Polyvinylchloride) noDOP with plasitcizer TEHTM (Tri-(2-ethylhexyl) trimellitate)
C41134	Drip chamber	●cap and lower part: SBC (Styrene Butadiene Copolymer) ●glue: THF (Tetrahydrofuran) ●adaptor for tube: PUR (Polyurethane)
C60931	Tube 3 x 5 mm	●PVC (Polyvinylchloride), plasticizer TOTM, stabiliser calcium / zinc, natural - unpigmented
J1010279		
C10275	Lower part of EN drip chamber for 3.0 x 5.0	●PVC (Polyvinylchloride) transparent, plasticizer TEHTM (Tri-2-ethylhexyl trimellitate; TOTM)
C11553	Solvent	●CHN (Cyclohexanone)
C30480	Bag Adapter	●ABS (Acrylonitrile-Butadiene-Styrene) ●lila / purple
J1011007		
C30313	Top filler (funnel)	●EVA (Ethylene-Vinyl-Acetate) Copolymer, BHT antioxidant ●Colourant blue ●Masterbatch Zinkstearate
C30327	Bag (foil tube) 1500 ml	●EVA (ethylene vinyl acetate copolymer)
C30328	Printing foil	●Polyester film with pigmented varnish coating (organic and inorganic pigments)
C30948	Compound tube 4.9 x 6.5 x 40 mm	●inner tube: PVC (Polyvinylchloride) with plasticizer TEHTM (Tri-(2-ethylhexyl) trimellitate) ●outer tube: PE (Polyethylene)
J1040192		
C30293	ENFit stopcock handle	●HDPE (high density polyethylene) with colourant

Article code	Article name	Material
C30294	ENFit stopcock housing	●Copolyester (BPA-free)
C30295	Silicone oil SILFAR 350	●PDMS (Polydimethylsiloxane)
C30297	ENFit stopcock handle FK	●HDPE (high density polyethylene) ●colourbatch purple
C30298	ENFit stopcock housing FK	●Copolyester (BPA-free)
J1040205		
C30293	ENFit stopcock handle	●HDPE (high density polyethylene) with colourant
C30294	ENFit stopcock housing	●Copolyester (BPA-free)
C30295	Silicone oil SILFAR 350	●PDMS (Polydimethylsiloxane)
C30297	ENFit stopcock handle FK	●HDPE (high density polyethylene) ●colourbatch purple
C30298	ENFit stopcock housing FK	●Copolyester (BPA-free)
J1040220S		
C11499	Petroleum ether	●N/A
C11503	Solvent	●THF (Tetrahydrofuran), also 1,4-Epoxy butane
C11511	Lubricant	●Aminofunctional Siloxane
C30776	ENFit female 5.0 mm	●Copolyester (BPA-free) ●RAL 4005 (violet), Colour concentrate
C30953	Tube 3.5 x 5.0 mm	●PVC (Polyvinylchloride) with plasticizer TOTM
Packaging		
	Carton 400 x 265 x 380 mm	●Corrugated cardboard
	PE-Band 90 x 30 x 0.05 mm	●HDPE (high density polyethylene)
	Adhesive tape	●BOPP (biaxially oriented polypropylene) film and rubber adhesive
	Roll ENFit label 105×148.8 mm	●Paper (blank white with violette bar) and Adhesive
	White paper for IFU printing	●Paper
	Compound foil 90µm	●Multilayer flat film PA (Polyamide) /adhesive layer / PE (Polyethylene)
	Peel paper Amika Sets ENFit ISO 200 x 240 mm	●Paper 60 g/m2
Sterilization		
	Sterilization gas	●Ethylene oxide
	Indicator tape for EO sterilization	●Process indicator tape for Ethylene Oxide (EO) sterilization