

Article code	7751715T
Article name acc. DoC	Amika Pump Set Bag, universal, ENFit
Class acc. MDR 2017/745	Ila

Article code	Article name	Material
C10419	Amika clamp	●PC (Polycarbonate) based on Bisphenole A ●Colorbatch lilac
C10549	Closure cap LL male	●PP (Polypropylene) ●Masterbatch (white)
C10578	Protective cap	●PP (Polypropylene)
C11503	Solvent	●THF (Tetrahydrofuran), also 1,4-Epoxy butane
C11504	Solvent / Lubricant	●Isopropyle alcohol
C11511	Lubricant	●Aminofunctional Siloxane
C11553	Solvent	●CHN (Cyclohexanone)
C30832	ENFit male-ENLock Universal connector purple	●ABS (Acrylonitrile-Butadiene-Styrene) ●Colourant lilac
	ENFit female oral / LL	●POM (Polyoxymethylene)
C60976	PVC tube Ø3,0 x Ø5,0	●PVC (Polyvinylchloride) compound with plasticizer DINCH
J1011026		
C30313	Top filler (funnel)	●EVA (Ethylene-Vinyl-Acetate) Copolymer, BHT antioxidant; ●Colourant blue; ●Masterbatch Zinc stearate;
C30327	Bag (foil tube) 1500 ml	●EVA (ethylene vinyl acetate copolymer)
	Printing foil	●Polyester film with pigmented varnish coating (organic and inorganic pigments)
C60975	DINCH-COEX tubing 4,9 X 6,5D	●Inner layer: PVC (Polyvinylchloride) with plasticizer DINCH; ●Outer layer: EVA (Ethylene-Vinyl-Acetate) Copolymer;
J1040193		
C30293	ENFit stopcock handle	●HDPE (high density polyethylene) with colourant
C30294	ENFit stopcock housing	●Copolyester (BPA-free)
C30295	Silicone oil SILFAR 350	●PDMS (Polydimethylsiloxane)
	ENFit stopcock handle FK	●HDPE (high density polyethylene) ●colourbatch purple
C30298	ENFit stopcock housing FK	●C90598 Copolyester (BPA-free)
J1040206		
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)
	ENFit stopcock handle FK	●HDPE (high density polyethylene) ●colourbatch purple
C30298	ENFit stopcock housing FK	●C90598 Copolyester (BPA-free)
J1040339		
C11553	Solvent	●CHN (Cyclohexanone)
	Bag Adapter	●ABS (Acrylonitrile-Butadiene-Styrene) ●lila / purple
C31180	Lower part of EN drip chamber for Ø3,0 x Ø5,0	●PVC (Polyvinylchloride) compound with plasticizer DINCH
J1040343		
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
	ENFit male-ENLock Universal connector purple	●ABS (Acrylonitrile-Butadiene-Styrene) ●Colourant lilac
C60977	PVC tube Ø3,5 x Ø5,0	●PVC (Polyvinylchloride) compound with plasticizer DEHT
Packaging		
	Carton 400 x 265 x 380 mm	●Corrugated cardboard, Flute C
	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
●THF (Tetrahydrofuran), also 1,4-Epoxy butane	Compound foil 90µm	●Multilayer flat film PA (Polyamide) /adhesive layer / PE (Polyethylene)
	Foil Amika Sets ENFit	●Foil
Sterilization		
	Sterilization gas, Nanchang	●Ethylene oxide (90%) + Carbon dioxide (10%)
	Indicator tape for EO sterilization	●Process indicator tape for Ethylene Oxide (EO) sterilization