

Article code	7751903 (M44310006)
Article name acc. DoC	Amika TwoLine EasyBag, ENFit
Class acc. MDR 2017/745	Ila

Article code	Article name	Material
C10419	Amika clamp	●PC (Polycarbonate) based on Bisphenole A ●Colorbatch lilac
C10467	Roller clamp	●housing: PP (Polypropylene) plus colourant blue ●wheel: HDPE (high density polyethylene)
C11503	Solvent	●THF (Tetrahydrofuran), also 1,4-Epoxy butane
C11515	Solvent	●MEK (Methylethylketone)
C30718	Y-piece	●PVC (Polyvinylchloride), NoDOP
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)
C30953	Tube 3.5 x 5.0 mm	●PVC (Polyvinylchloride) with plasticizer TOTM
C60931	Tube 3 x 5 mm	●PVC (Polyvinylchloride), plasticizer TOTM, stabiliser calcium / zinc, natural - unpigmented
J1040192		
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)
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	
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

Article code	Article name	Material
C30953	Tube 3.5 x 5.0 mm	●PVC (Polyvinylchloride) with plasticizer TOTM
J1040253		
C10594	Protective cap for ENPlus	●PP (Polypropylene)
C10897	Sealing for Cross spike	●LDPE (low density polyethylene) + EPE (foamed PE)
C11503	Solvent	●THF (Tetrahydrofuran), also 1,4-Epoxy butane
C30106	Retainer nut ENPlus	●PP (Polypropylene) ●Colourant lilac
C30820	ENPlus spike	●ABS (Acrylonitrile Butadiene Styrene) ●Carrier: Novodur P2H-AT ●Components: Inorganic and organic pigments
C41134	Drip chamber	●cap and lower part: SBC (Styrene Butadiene Copolymer) ●glue: THF (Tetrahydrofuran) ●adaptor for tube: PUR (Polyurethane)
J1040277		
C10275	Lower part of EN drip chamber for 3.0 x 5.0	● PVC (Polyvinylchloride) transparent, plasticizer TEHTM (Tri-2-ethylhexyl trimellitate; TOTM)
C10594	Protective cap for ENPlus	●PP (Polypropylene)
C10897	Sealing for Cross spike	●LDPE (low density polyethylene) + EPE (foamed PE)
C11553	Solvent	●CHN (Cyclohexanone)
C30478	Union nut EN	●PP (Polypropylene) (50 %) ●Resin ester polymer (carrier material) + pigment dispersion
C30479	EN Drip chamber upper part	●ABS (Acrylonitrile-Butadiene-Styrene) ●Pigment ABS purple
J1040288		
C10594	Protective cap for ENPlus	●PP (Polypropylene)
C10897	Sealing for Cross spike	●LDPE (low density polyethylene) + EPE (foamed PE)
C11503	Solvent	●THF (Tetrahydrofuran), also 1,4-Epoxy butane
C30106	Retainer nut ENPlus	●PP (Polypropylene) ●Colourant lilac
C30700	ENPlus spike	●ABS (Acrylonitrile-Butadiene-Styrene) ●Pigment ABS purple
C41134	Drip chamber	●cap and lower part: SBC (Styrene Butadiene Copolymer) ●glue: THF (Tetrahydrofuran) ●adaptor for tube: PUR (Polyurethane)
Packaging		
	Carton box	●Cardboard
	PE-Band 90 x 30 x 0.05 mm	●HDPE (high density polyethylene)

Article code	Article name	Material
	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 100x225mm	●Paper 60 g/m2
Sterilization		
	Sterilization gas	●Ethylene oxide
	Indicator tape for EO sterilization	●Process indicator tape for Ethylene Oxide (EO) sterilization