

Article code	7751902 (M44310004)
Article name acc. DoC	Amika Varioline, 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
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)
C31592	Tinopal Optical Brightener	●2,5-thiophenediylbis(5-tert-butyl-1,3-benzoxazole), color: Slight greenish yellow
C60931	Tube 3 x 5 mm	●PVC (Polyvinylchloride), plasticizer TOTM, stabiliser calcium / zinc, natural - unpigmented
J1010280		
C10275	Lower part of EN drip chamber for 3.0 x 5.0	●PVC (Polyvinylchloride) transparent, plasticizer TEHTM (Tri-2-ethylhexyl trimellitate; TOTM)
C10897	Sealing for Cross spike	●LDPE (low density polyethylene) + EPE (foamed PE)
C11553	Solvent	●CHN (Cyclohexanone)
C30478	Union nut EN	●PP (Polypropylene) ●Resin ester polymer (carrier material) + pigment dispersion
C30479	EN Drip chamber upper part	●ABS (Acrylonitrile-Butadiene-Styrene) ●Pigment ABS purple
J1010767		
C10330	Air ventilation plug	●ABS (Acrylonitrile Butadiene Styrene) ●Colourant white, ABS (Acrylonitrile Butadiene Styrene)-carrier
C10824	Bacteria filter	●glass microfiber filter
C10825	Bacteria filter band	●hydrophobic glass microfibre
C11120	Lid valve	●Silicone
C30032	Insert ENPlus	●HDPE (high density polyethylene) ●Colourant lilac
C30058	Body Varioline Adapter ENPlus	●LDPE (low density polyethylene) ●PE (Polyethylene) ●Colourant lilac ●lubricant demoulding aid
J1040189		

Article code	Article name	Material
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)
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	●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
J1040285		
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

Article code	Article name	Material
C41134	Drip chamber	● cap and lower part: SBC (Styrene Butadiene Copolymer) ● glue: THF (Tetrahydrofuran) ● adaptor for tube: PUR (Polyurethane)
J1040286		
C10333	Air ventilation plug	● ABS (Acrylonitrile-Butadiene-Styrene) ● Colourant white, ABS (Acrylonitrile-Butadiene-Styrene)-carrier
C10824	Bacteria filter	● glass microfiber filter
C11120	Lid valve	● Silicone
C30032	Insert ENPlus	● HDPE (high density polyethylene) ● Colourant lilac
C30058	Body Varioline Adapter ENPlus	● LDPE (low density polyethylene) ● PE (Polyethylene) ● Colourant lilac ● lubricant demoulding aid
Packaging		
	Tubular foil for packaging	● Film 500m x 350 mm x 40 µm ● Mixture of different Polyolefines PE (Polyethylene), LDPE (Polyethylene, low density), transparent
	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
	Carton 397 x 230 x 205 mm	● Paper
	Compound foil 90µm	● Multilayer flat film PA (Polyamide) /adhesive layer / PE (Polyethylene)
	PE-Band	● HDPE (high density polyethylene)
	peel paper Amika Sets ENFit ISO 100x225mm	● Paper 60 g/m ²
Sterilization		
	Sterilization gas	● Ethylene oxide
	Indicator tape for EO sterilization	● Process indicator tape for Ethylene Oxide (EO) sterilization