

Article code	7751915
Article name acc. DoC	Amika Bag mobile with cover, 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
C11553	Solvent	●CHN (Cyclohexanone)
C11909	Patient ID card	●self-adhesive paper sheet product for offset printing woodfree offset paper, white, 80 g/m² - FKN: paper, Sheetfed Offset Ink, self-adhesive glue
C30601	Adaptor	●MABS (Methylmethacrylate Acrylonitrile Butadiene Styrene)
C30622	Transition adaptor	●PUR (Polyurethane)
C30844	ENFit male cap, vented	●PP (Polypropylene)
C30931	Tube 3 x 5 mm	●PVC (Polyvinylchloride) noDOP with plasticizer TEHTM (Tri-(2-ethylhexyl) trimellitate)
C30949	Tube 2.5 x 4.22 mm	●PVC (Polyvinylchloride)
C30953	Tube 3.5 x 5.0 mm	●PVC (Polyvinylchloride) with plasticizer TOTM
C31106	Bag (foil tube) 1000 ml	●Connector TOTM: PVC -TOTM (Polyvinylchloride) ●blue stopper: PVC - TOTM (Polyvinylchloride) ●medical foil 0.35 mm: PVC (Polyvinylchloride) ●printing foil blue: Polyester film ((PET) (Polyethyleneterephthalate)) with pigmented lacquer
C60931	Tube 3 x 5 mm	●PVC (Polyvinylchloride), plasticizer TOTM, stabiliser calcium / zinc, natural - unpigmented
J1011016		
C31352	PVC Film Transfufol 410 x 0.35 mm PVC 3224 seta	• PVC with TEHTM, natural colour
C31353	Stamping film“Colorit P 925”	• Polyester film with pigmented lacquer coating (organice and / or inorganic pigments) • Polyester terephthalate (PET)
C31590	Elbow connector	●PVC with TEHTM, natural colourless
C31591	PVC filling plug	• PVC with TEHTM • 2% Colour batch blue, carrier PVC
J1040202		
C30293	ENFit stopcock handle	●HDPE (high density polyethylene) with colourant
C30294	ENFit stopcock housing	●Copolyester (BPA-free)

Article code	Article name	Material
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)
C30823	ENFit female cap	●HDPE (high density Polyethylene) ●colourant violet
C30878	ENFit Stopcock 5.0 mm (open)	●housing: Copolyester (BPA-free) ●handle: HDPE (high density polyethylene) with colourant ●PDMS (Polydimethylsiloxane)
C30897	Strap for ENFit male connector	●LDPE (Low density polyethylene)
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 box 391 x 288 x 209 mm	●Corrugated cardboard
	Compound foil 70 µm	●PA (Polyamide) / adhesive layer / PE (Polyethylene)
	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
	Oberfolie Amika	●Paper 60 g/m2
Sterilization		
	Sterilization gas	●Ethylene oxide
	Indicator tape for EO sterilization	●Process indicator tape for Ethylene Oxide (EO) sterilization