

Article code	7751938
Article name acc. DoC	GraviSet Bag, ENFit
Class acc. MDR 2017/745	Is

Article code	Article name	Material
C10467	Roller clamp	●housing: PP (Polypropylene) plus colourant blue ●wheel: HDPE (high density polyethylene)
C11503	Solvent	●THF (Tetrahydrofuran), also 1,4-Epoxy butane
C11504	Solvent / Lubricant	●Isopropyle alcohol
C11511	Lubricant	●Aminofunctional Siloxane
C11553	Solvent	●CHN (Cyclohexanone)
C60977	PVC tube Ø3,5 x Ø5,0	●C90774: PVC (Polyvinylchloride) compound with plasticizer DEHT
J1011026		
C30313	Top filler (funnel)	●C90340; EVA (Ethylene-Vinyl-Acetate) Copolymer, BHT antioxidant; ●C90395: Colourant blue; ●C90392: Masterbatch Zinc stearate;
C30327	Bag (foil tube) 1500 ml	●EVA (ethylene vinyl acetate copolymer)
C30328	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;
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	●C90583 HDPE (high density polyethylene) ●C90584 colourbatch purple
C30298	ENFit stopcock housing FK	●C90598 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	●C90583 HDPE (high density polyethylene) ●C90584 colourbatch purple
C30298	ENFit stopcock housing FK	●C90598 Copolyester (BPA-free)

Article code	Article name	Material
J1040339		
C11553	Solvent	●CHN (Cyclohexanone),
C30480	Bag Adapter	●C90735 ABS (Acrylonitrile-Butadiene-Styrene) ●C90734 lila / purple
C31180	Lower part of EN drip chamber for Ø3,0 x Ø5,0	●C90772: PVC (Polyvinylchloride) compound with plasticizer DINCH
J1040342		
C11499	Petroleum ether	●N/A
C11503	Solvent	●THF (Tetrahydrofuran), also 1,4-Epoxy butane
C11511	Lubricant	●Aminofunctional Siloxane
C30776	ENFit female 5.0 mm	●C90598: Copolyester (BPA-free) ●C90599: RAL 4005 (violet), Colour concentrate
C60977	PVC tube Ø3,5 x Ø5,0	●C90774: PVC (Polyvinylchloride) compound with plasticizer DEHT
Packaging		
C11055A	Carton 400 x 265 x 380 mm	●Corrugated cardboard
C11521	PE-Band 90 x 30 x 0.05 mm	●HDPE (high density polyethylene)
C12184	Adhesive tape	●BOPP (biaxially oriented polypropylene) film and rubber adhesive
C12704	Roll ENFit label 105×148.8 mm	●Paper (blank white with violette bar) and Adhesive
C12972	White paper for IFU printing	●Paper
C31301	Compound foil 90µm	●Multilayer flat film PA (Polyamide) /adhesive layer / PE (Polyethylene)
C64504	top foil Gravi ENFit, 200 x 240 mm	●top foil
Sterilization		
C11520CN	Sterilization gas, Nanchang	●Ethylene oxide (90%) + Carbon dioxide (10%)
C11525	Indicator tape for EO sterilization	●Process indicator tape for Ethylene Oxide (EO) sterilization