

Article code	M46421820
Article name acc. DoC	Ambix nova ambulatory Set
Class acc. MDR 2017/745	Ila

Article code	Article name	Material
C10564	Protective cap LL pos. with 1.2 µm filter	• Housing: PP (Polypropylene) + Masterbatch • Filter: Haemophobic/hydrophobic membrane; 1,2 µm PVDF (Polyvinylidene difluoride) Fortex Membrane
C10747	Back check valve	• Housing upper part: MABS (Methylmethacrylate Acrylonitrile Butadiene Styrene), white • Housing lower part: SAN (Styrene-Acrylonitrile), • Colourant: white • Valve: Silicone rubber
C10898	Filter Speed Flow 1,2 µm	• Housing: MBS (Methylacrylate / butadiene/styrene) • fluid filter: 1.2 µm hydrophilic PES Polyethersulfone) • air filter: 0.03 µm hydrophobic PTFE (Polytetrafluoroethylene)
C11503	Solvent	• THF (Tetrahydrofuran), also 1,4-Epoxy butane
C11553	Solvent	• CHN (Cyclohexanone)
C21650	Non-vented spike	• Protective Cap: PE (Polyethylene) • Spike: ABS (Acrylonitrile Butadiene Styrene), white
C30949	Tube 2.5 x 4.22 mm	• PVC (Polyvinylchloride)
J1010902		
C11503	Solvent	• THF (Tetrahydrofuran), also 1,4-Epoxy butane,
C11515	Solvent	• MEK (Methylethylketone)
C30631	Connection piece	• MABS (Methylmethacrylate Acrylonitrile Butadiene Styrene) • (2%) carrier material ABS (Acrylonitrile Butadiene Styrene) with anorganic and organic colour pigments (blue)
C30632	Pump connector upstream	• MABS (Methylmethacrylate Acrylonitrile Butadiene Styrene) • (2%) carrier material PS (Polystyrene) with anorganic and organic pigments and dyes (light green)
C30650	Antikink	• PP (Polypropylene) • (2%) Carrier material PP with organic and inorganic colourants
C31646	Ambix Nova Clamp	• Polycarbonate • 2% Masterbatch blue (Carrier: Polycarbonate)
C60936	noDOP PVC-tube ø 3,0 x ø 5,0 x	• PVC (Polyvinylchloride) with plasticizer TEHTM

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	195mm	
Packaging		
	Folding box 400 x 220 x 95 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)
	White paper for IFU printing	• 100% wood pulp
	Roll Label 105 x 148 mm	• Paper (blank white) and Adhesive
	Paper Ambix nova ambulatory Sets	•
Sterilization		
	Sterilization gas, Nanchang	• Ethylene oxide (90%) + Carbon dioxide (10%)
	Indicator tape for EO sterilization	Process indicator tape for Ethylene Oxide (EO) • sterilization