

**SPECIFICATION**  
**ROMED LATEX EXTERNAL MALE CATHETERS**  
**REF: EXCAT – S/M/L/XL/XXL**



Medical device conform MDR (EU) 2017/745

External male catheter, pre powdered, disposable					
ITEM No	EXCAT-S	EXCAT-M	EXCAT-L	EXCAT-XL	EXCAT-XXL
SIZE (Diameter, mm)	20	25	30	35	40
OVERALL LENGTH (mm)	165 ±4mm	167±4mm	170±4mm	183±4mm	187±4mm
WIDTH (Diameter mm)	20 ±1	25±1	30±1	35±1	40±1
THICKNESS (mm)	0.10 - 1.20				
WEIGHT (g)	2.0 ± 0.5	2.8±0.5	3.7±0.5	4.5±0.5	5.3±0.5
PHYSICAL PROPERTIES	Tensile strength		18MPa	≥14MPa	
	Elongation		800%	≥600%	
SAMPLING PLAN	ISO 2859-1 Manufactured in compliance with current GMP requirement				
	Major	AQL 2.5		S-4	
	Minor	AQL 4.0		S-2	
MAJOR & MINOR	Major: Visual holes, latex lumps, chunks				
	Minor: Incorrect size, improper beading, excessive powder, fails tensile, strength of elongation, improper dimensions or thickness				

Caution: This product contains natural rubber latex which may cause allergic reactions.

<b>COMPONENTS OF LATEX EXTERNAL MALE CATHETERS COMPONENTS</b>	<b>%</b>
Absorbo cornstarch dusting powder USP	8.19%
Zinc Oxide	0.50%
Colloidal Sulphur 95	0.72%
ZDEC (Zinc Diethyldithiocarbamate)	1.00%
Vultamol	0.50%
Potassium Hydroxide Flake	0.04%
Edible Casein	0.58%
Calcium Chloride flakes (Anhydrous)	0.03%
White colour	0.64%
Calcium nitrate	0.01%
Teric 320	0.03%
Trisodium Phosphate	0.05%
Newcol 565H (P.O.E. Nonly Phenyl Ether)	0.21%
Forestall Ageing Solvent	0.08%
Antiseptic	0.01%
Advance Ageing	0.01%
High Ammonia Latex (Segun ISO-2004-1979)	87.40%

Packing: per piece in a plastic bag, 50 pieces in an inner box, 1000 pieces in a carton.