

Product specifications - Condoms

1. Description

Condoms translucent smooth surface, lubricated, 0.065 + 0.015mm – 0.020mm thickness and minimum 180 mm length¹. Width as per article description ± 2 mm

2. Producer and article code

Producer : Karex Industries Sdn Bhd
Manufacturing site : Karex Industries Sdn Bhd., PTD 7906 & 7907, Taman Pontian Jaya, Batu 34, Jalan Johor, 82000 Pontian, Johor, Malaysia
Product codes : G600-G20 Condoms male WHO/ISO4074 52mm squarefoil
G600-G21 Condoms male WHO/ISO4074 53mm squarefoil

3. Specifications

According ISO 4074:2015 and WHO Male Latex Condom specification, Prequalification and Guideline for Procurement, 2010 / rev April 2013

Quality materials : Complying with the requirements of the applicable portions of the US Code of Federal Regulations (USCFR) 21 or its equivalent.
- Condom material : Natural rubber latex
- Lubricant : Silicone oil 350cST (dimethyl-siloxane)

General requirements:

Testing by visual inspection or ISO 4074 test protocols:

Latex : No grit or discoloration, no toxic or harmful substances (ISO 10993-5 cytotoxicity, ISO 10993-10 irritation and sensitization, ISO 10993-11 systemic toxicity), free of embedded solid impurities and discoloration.
Bead : A thickened ring of latex at the open end should be present.
Shape : Straight and parallel-sided without constrictions, and with a visible shoulder leading to a reservoir pouch at the tip
Texture : Smooth throughout.
Colour and clarity : Translucent (clear) and without added colouring.
Individual packaging : Opaque, square package, structure of foil PET / Al / PE / LLDPE:
- PET
- Aluminium
- PE
- LLDPE
- Total weight
- Total thickness
Workmanship : Condoms and packaging free from defects.

¹ Length as recommended by WHO model specification 2010/ Amd 1:2013

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Design requirements:

specification	inspection level	Limits	AQL
Length ²	S-2 (13 pcs)	NLT 180 mm	1.0
Width	S-2 (13 pcs)	Claimed width \pm 2 mm	1.0
Thickness ³	S-2	0.065 + 0.015mm – 0.020mm	1.0
Quantity of lubricant ⁴	S-2	550 \pm 150 mg	4.0
Burst volume	G-1	NLT 18.0 liter	1.5
Pressure	G-1	NLT 1.00 kPa	1.5
Freedom from Holes	G-1	No leakage	0.25
Visible defects	G-1	Visual inspection Free from defects	Critical: 0.4
			Non-critical: 2.5
Package integrity	S-3	No leakage after 1 min vacuum	2.5
Individual package materials and markings	S-3	Visual inspection on the package quality	2.5
Individual containers with visibly open seals	G-1	No open seal	0.4

4. Storage

Store in a cool dry place away from heat and direct sunlight

5. Shelf life

Five (5) years; Batch and manufacturing date and shelf life printed on foil and packaging