


Manufacturer	 MAK GİRİSİM DİŞ TİCARET LTD. ŞTİ.
Address	Buyuk Sinan Mahallesi. Cicekci Sokak No:7/202 Karatay/KONYA-TURKEY bilgi@makgirisim.com // Tel:+90 332 606 06 96
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Manufacturer	MAK GIRISIM DIS TICARET LIMITED SIRKETI
Address	Büyük Sinan Mah. Çiçekci Sok. No:7/202 Karatay / KONYA - TÜRKİYE

Sample Definition	Surgical Drapes And Gowns
Standards	EN 13795-1



Characteristic	Microbial Penetration – Dry		
Test method	EN ISO 22612		
Unit	CFU		
Critical product area	Not required		
	Fulfilled <input type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input checked="" type="checkbox"/>
Less critical product area	≤ 300 (180)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
EN ISO 22612 // Test method for resistance to dry microbial penetration			

Characteristic	Microbial penetration – Wet		
Test method	EN ISO 22610		
Unit	I _B		
Critical product area	6,00		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
Less critical product area	Not required		
	Fulfilled <input type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input checked="" type="checkbox"/>
EN ISO 22610 // Test method to determine the resistance to wet bacterial penetration			

Characteristic	Cleanliness microbial / Bioburden		
Test method	EN ISO 11737-1		
Unit	CFU/100 cm ²		
Critical product area	≤ 300		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
Less critical product area	≤ 300		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
EN ISO 11737-1 // Determination of a population of microorganisms on products			

Characteristic	Particle Release		
Test method	EN ISO 9073-10		
Unit	log ₁₀ (lint count)		
Critical product area	≤ 4,00 (3,00)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
Less critical product area	≤ 4,00 (3,00)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
EN ISO 9073-10 // Lint and other particles generation in the dry state			

Characteristic	Liquid Penetration		
Test method	EN ISO 811		
Unit	cm H ₂ O		
Critical product area	≥ 100 (140)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
Less critical product area	≥ 100 (140)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
EN ISO 811 // Hydrostatic pressure test			

Characteristic	Bursting strength - Dry		
Test method	EN ISO 13938-1		
Unit	kPa		
Critical product area	≥ 40 (70)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
Less critical product area	≥ 40 (70)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
EN ISO 13938-1 // Hydraulic method for determination of bursting strength and bursting distension			

Characteristic	Bursting strength – Wet		
Test method	EN ISO 13938-1		
Unit	kPa		
Critical product area	≥ 40 (70)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
Less critical product area	Not required		
	Fulfilled <input type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input checked="" type="checkbox"/>
EN ISO 13938-1 // Hydraulic method for determination of bursting strength and bursting distension			

Characteristic	Tensile strength – Dry		
Test method	EN 29073-3		
Unit	N		
Critical product area	≥ 20 (34)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
Less critical product area	≥ 20 (34)		
	Fulfilled <input type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input checked="" type="checkbox"/>
EN 29073-3 // Determination Of Tensile Strength And Elongation			

Characteristic	Tensile strength - Wet		
Test method	EN 29073-3		
Unit	N		
Critical product area	≥ 20 (34)		
	Fulfilled <input checked="" type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input type="checkbox"/>
Less critical product area	Not required		
	Fulfilled <input type="checkbox"/>	Unfulfilled <input type="checkbox"/>	N/A <input checked="" type="checkbox"/>
EN 29073-3 // Determination Of Tensile Strength And Elongation			

- This document has been prepared at the request of the company.
- The conformity of the information and values given to the standard has been reported.
- This evaluation has been checked for compliance with the requirements of the standard.
- Engineering service was provided with this report.

Preparing the document

Mr. Besim BOZDAŞ
Industry Engineer M.Sc.



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