



**MHKMEDİKAL**  
TEKSTİL

**MHK Medikal Tekstil San. Ve. Tic. Ltd. Şti.**

## Product Analysis Certificate

We, MHK Medikal Tekstil San. Ve. Tic. Ltd. Şti.. as manufacturer, that the following products' tests reports are acceptable.

**Product Name** : Single Gown

PRODUCT NAME		Disposable Surgical Gown S/M/L/XL					
Characteristic	Test Method	Units	High Performance (reinforced gown)				Evaluation
			Critical Zone		Non Critical Zone		
			Standard	Test result	Standard	test result	
Resistance microbial penetration - dry	EN ISO 22612	CFU	N/A	-	<= 300	18	Acceptable
Resistance microbial penetration - wet	EN ISO 22610	BI	6	6	N/A	-	Acceptable
Microbial Cleanliness	EN ISO 11737-1	CFU/100 cm <sup>2</sup>	<= 300	27	<= 300	27	Acceptable
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	<= 3,5	3,4	<= 3,5	3,4	Acceptable
Linting	EN ISO 9073-10	log10	<= 4,0	3,6	<= 4,0	3,6	Acceptable
Resistance to liquid penetration	EN 20811	cm H2O	>= 100	100	>= 10	100	Acceptable
Bursting strength — Dry	EN ISO 13938-1	kPa	>= 40	123	>= 40	123	Acceptable
Bursting strength — Wet	EN ISO 13938-1	kPa	>= 40	122	N/A	-	Acceptable
Tensile strength — Dry (CD / MD)	EN 29073-3	N	>= 20	103	>= 20	103	Acceptable



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### Biocompatibility

Sensitization ( Biocompatibility)	<b>Not Sensitized</b>	According to EN ISO 10993-5
In Vitro Cytotoxicity (Biocompatibility)	<b>Not Cytotoxic</b>	According to EN ISO 10993-5
Irritation (Biocompatibility)	<b>Not Irritated</b>	According to EN ISO 10993-10

### Quality Control

Quality Control Parameters	Report	Specification
Sterility Control	<b>Passed (No Growth)</b>	According to EN 11135-1, EN 11737-2
Cleaning Appearance	<b>Passed</b>	Should be clean
Raw material Control	<b>Passed</b>	The right raw material should be used
Size Control	<b>Passed</b>	The size should be $\pm 3$ cm
Adhesion Control	<b>Passed</b>	The layers of the drape should not be Separated.

\*OUR PRODUCTS DO NOT CONTAIN LATEX.

Approved By Quality Management Representative / 2020/11/11 / TURKEY

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