CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name	: Nurel Medikal San. ve Tic. A.Ş.
Company Address	: Dosab Karanfil Sok. No:4.B. Osmangazi BURSA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex V
Product	: Sterile Surgical Gowns, Surgical Drapes and Drape Sets - Class Is
GMDN	: 47783, 35778, 35092
Certificate Number	: M.2016.106.7196
Report Number	: MD.3336.YB
Initial Assessment Date	: 15.07.2016
Registration Date	: 23.11.2016
Recertification Assessment Date	: 02.10.2019
Reissue Date / No	: 04.05.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM APPROV 2292

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

Digitally signed by Granaci Boris
Date: 2023.11.09 12:13:41 EET
Reason: MoldSign Signature
Location: Moldova

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

akssert

CERTIFICATE

Nurel Medikal San ve Tic A.Ş.

Dosab Karanfil Sokak No:4.B. Osmangazi BURSA / TURKEY

ISO 13485:2016

Scope: Manufacture and sales of sterile and non-sterile disposable surgical drapes, surgical gowns, surgical drape packs, examination gowns and apparels, clean air suits for patients, sterile and non-sterile plastic medical devices and their sets, sterilization of the medical devices

Hereby, AKSSERT Audit and Certification Ltd. Co., certificates that the above stated company gave the appropriate management system according to the requirements of the above standard. This certificate valid for 3 years since the decision date as long as the system is effectively maintaned and surveillance audits are carried out. The validity of certificate can be checked through www.akssert.com, www.jas-anz.org/register. The Certificate is property of AKSSERT Audit and Certification Ltd. Co. and shall be returned if requested.
The reference standard is ISO 13485:2016

AKSSERT Audit and
Certification Ltd. Co.

akssert JAS-ANZ

Certificate Number : 85330
Registration Date : 05.12.2017

Reissue Date : 24.11.2020
Expiry Date : 04.12.2023

Address: Mustafa Kemal Mah. 2157/1 Sokak No:5/7 Çankaya / ANKARA– TÜRKİYE
Phone: +90 312 284 99 44(pbx)
E-mail: info@akssert.com **Web:** www.akssert.com

NUREL® medikal DISPOSABLE SURGICAL GOWNS & SURGICAL DRAPPES

EUROSET®

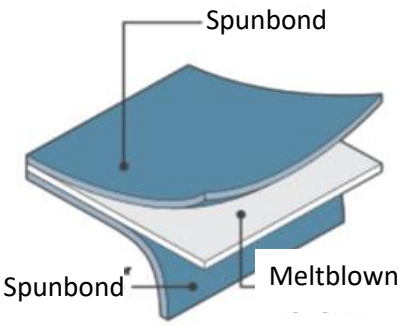
KFR 050 RAW MATERIAL TECHNICAL DATA SHEET

MATERIAL NAME	40 GSM SMMS FOBIK S1115 MONO SPUNBOND
NUREL, RAW MATERİAL CODE	NHM-1010037
SUPPLIER CODE	30018

TECHNICAL SPECIFICATIONS

PROPERTIES	VALUE	TOLERANCE	TEST METHOD
Basis Weight (g/m²)	40	±5%	WSP130.1
MD Mukavemet @ Peak MD Tensile @ Peak (N)	100	≥80	WSP110.4
MD Sünme @ Peak MD Elongation @ Peak (%)	40	≥60	WSP110.4/
CD Mukavemet @ Peak CD Tensile @ Peak (N)	60	≥50	WSP110.4/
CD Sünme @ Peak CD Elongation @ Peak (%)	-	≥60	WSP110.4/
Su Sütunu / Hydrostatic Head (mmWC)	330	≥300	WSP80.6/

COMPOSITION: Spunbond+Meltblown+Spunbond(TOTAL WEIGHT 40GSM±5%)



Roll Tolerance:
Length : - 0 / +5% against target lenght
Width : Up to 161cm in width = -0mm/+5mm
Over 159 cm in width = - mm/+10 S

OTHER SPECIFCATIONS

REMARKS: This test has been performed under laboratory conditions, by Material Manufacturer. Results may change according to fabric type and production conditions. Pre-application at your facilities is strictly advised.

Turkey Discover the potential

NUREL® medikal DISPOSABLE SURGICAL GOWNS & SURGICAL DRAPPES

EUROSET®

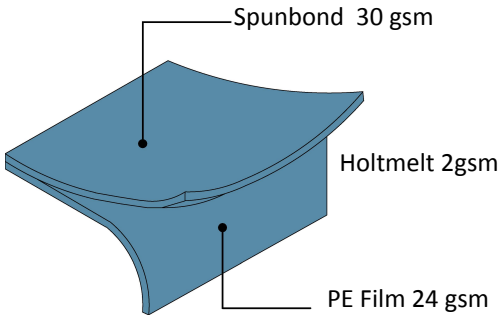
KFR 050 RAW MATERIAL TECHNICAL DATA SHEET

MATERIAL NAME	56 GSM PHILIC SB LAMINATED TWO LAYERS FABRIC
NUREL, RAW MATERİAL CODE	NHM-1020087
SUPPLIER CODE	30580

TECHNICAL SPECIFICATIONS

PROPERTIES	VALUE	TOLERANCE	TEST METHOD
GSM Grammage (g/m²)	56	≥52	WSP 130.1
MD Mukavemet MD Tensile at Peak (N/ 25mm)	45	≥40	WSP 110.4
MD Sünme MD Elongation at peak (%)	50	≥30	WSP 110.4
CD Mukavemet CD Tensile at Peak (N/ 25mm)	28	≥23	WSP 110.4
CD Sünme CD Elongation at Peak (%)	65	≥45	WSP 110.4
Yapışma Kuvveti (Soyulma) Lamination Strength (N/ 25mm)	1,0	≥0,7	WSP 401.0
Su Sütunu Hydrostatic Head (mmSS)	2750	≥2500	WSP 80.6
Korona Corona (Dyne)	38	≥38	ASTM D2578
Sıvı Penatrasyonuna Direnç Resistance to Liquid Penetration (cm/H2O)	100	≥20	EN 20811
Temizlik-Mikrobik Clean-Microbial (cfu/g)	<15	-	WSP 80.6

COMPOSITION: 30 gsm Mavi Filik NW + 2 gsm Tutkal + 24 gsm Mavi NBRT Film 30 gsm Blue Hydrophilic NW + 2 gsm Hotmelt + 24 gsm Blue NBRT Film



Roll Tolerance:

Length : - 0/ +5% against target lenght

Width : Up to 150 cm in width = -0mm/+5mm

Over 150 cm in width = - 0mm/+10 S

OTHER SPECIFCATIONS

REMARKS: This test has been performed under laboratory conditions, by Material Manufacturer. Results may change according to fabric type and production conditions. Pre-application at your facilities is strictly advised.

Turkey Discover the potential