

DATASHEET

NONSTERILE MEDICAL BEDSHEET		
ITEM	SIZE	PC
Medical Bedsheet	150x200	1



- **REF:** 22681
- **Material:** SMS
- **Material GSM:** 35 Gsm
- Single use, Antiallergenic, Breathable, Non-absorbable, Liquid repellent
- High tensile strength not to break
- No elastic on bedsheet
- Non-Linting
- Latex free
- Individual packaging
- 1 pc per PE bag
- **Sterilization Type:** Nonsterile
- **Shelf Life:** 5 years
- **Colour:** Blue
- **Tolerance:** +/- 2%

SENMED MEDİKAL LTD.ŞTİ.
Zeytinli Mah. 79006 Sk. Köknar Tower No.3/8
Tel.: +90.544 797 48 72 - Şehitkamil/GAZİANTEP
Tic.Sic.No.59330 Mersis No.0761097672400001
Şehitkamil V.D. 761 097 6724

DATASHEET

NONSTERILE MEDICAL BEDSHEET		
ITEM	SIZE	PC
Medical Bedsheet	50x40	10

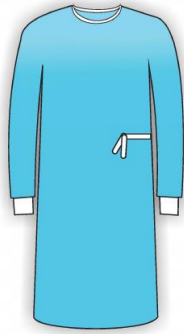


- **REF:** 22682
- **Material:** SMS
- **Material GSM:** 35 Gsm
- Single use, Antiallergenic, Breathable, Non-absorbable, Liquid repellent
- High tensile strength not to break
- No elastic on bedsheet
- Non-Linting
- Latex free
- 10 pcs per PE bag
- **Sterilization Type:** Nonsterile
- **Shelf Life:** 5 years
- **Colour:** Blue

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DATA SHEET

DISPOSABLE NONSTERILE MEDICAL GOWN		
CONTENT	SIZE	QTY
Medical Gown	S – M – L – XL – XXL – 3XL	1 pc



- **Material:** SMS 35 Gr
- Single use, Antiallergenic, Breathable, Liquid repellent
- High tensile strength not to break when dressed
- Non-Linting, Long sleeves
- Back ties
- Adjustable Soft knitted cuffs on sleeves
- Neck fastening with tie
- 2 Belts around waist
- Latex free
- **Sterilization Type:** Non-Sterile
- **Shelf Life:** 5 years
- **Length of sizes;**
 - Size S – 110 cm
 - Size M – 110 cm
 - Size L – 115 cm
 - Size XL – 120 cm
 - Size XXL – 130 cm
 - Size 3XL – 140 cm
- **REF Codes;**
 - Size S – 22683
 - Size M – 22684
 - Size L – 22685
 - Size XL – 22686
 - Size XXL – 22687
 - Size 3XL – 22688
- Tolerance: +/- 2%
- Single Packing, 1 pc per PE pack

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CATALOG

 A full-length image of a person wearing a light blue isolation gown. The gown has long sleeves with elastic cuffs, a front closure, and a full-length front panel.	ISOLATION GOWN • Material: SS / PP • Various grammages are available • Available Colours: Blue / White / Yellow • Available size: S / M / L / XL / XXL / XXXL • Single packed • Elastic wrist or knitted wrist
 A full-length image of a blue protective gown. It has long sleeves with elastic cuffs, a front closure, and a full-length front panel.	PROTECTIVE GOWN • Material: SMS / SMMS / SSMMS • Various grammages are available • Available Colours: Blue / Green • Available size: S / M / L / XL / XXL / XXXL • Single packed • Elastic wrist or knitted wrist



LAMINATED GOWN

- Material: Laminated & Breathable
- Various grammages are available
- Available Colours: Blue / White
- Available size: S / M / L / XL / XXL / XXXL
- Single packed
- Elastic wrist or knitted wrist



SCRUB SUITS

- Material: Various are available
- Various grammages are available
- Available Colours: Blue / Green
- Available size: S / M / L / XL / XXL / XXXL
- Single packed



COVERALL TYPE 5/6

- Material: Various are available
- Various grammages are available
- Available Colours: White / Blue
- Available size: S / M / L / XL / XXL / XXXL
- Single packed

 A full-body white protective coverall with blue elastic cuffs, ankle bands, and a hood. It features a blue vertical seam down the center and blue horizontal bands across the chest and waist.	COVERALL TYPE 3/4 • Material: Various are available • Various grammages are available • Available Colours: White / Blue • Available size: S / M / L / XL / XXL / XXXL • Single packed
 A blue long-sleeved disposable jacket or lab coat with a white V-neck collar, white elastic cuffs, and two white elasticated hems at the bottom. It has two large white rectangular pockets on the front.	DISPOSABLE JACKET / LAB COAT • Material: Various available • Various grammages are available • Available Colours: Blue / Green • Available size: S / M / L / XL / XXL / XXXL • Single packed • Knitted, soft, elastic collar • Knitted, soft, elastic cuffs
 A blue short-sleeved patient gown with a white V-neck collar and a white elasticated hem at the bottom.	PATIENT GOWN • Material: SS / SMS / SMMS / SSMMS • Various grammages are available • Available Colours: Blue / Green • Available size: S / M / L / XL / XXL / XXXL • Single packed



NON-SLIP LAMINATED BOOT COVER

- Material: Various are available
- Various grammages are available
- Available Colours: White / Blue
- Available size: S / M / L / XL / XXL / XXXL
- Single packed



NONWOVEN SHOE COVER

- Material: Various are available
- Various grammages are available
- Available Colours: White / Blue
- Available size: S / M / L / XL / XXL / XXXL
- Single packed



COLONOSOPY SHORTS AND PANTS

- Material: SMS / SMMS / SSMMS
- Various grammages are available
- Available Colours: Blue
- Available size: S / M / L / XL / XXL / XXXL
- Single packed



DISPOSABLE BEDSHEET

- Material: Various are available (PP, SMS, Laminated or Non-Laminated)
- Various grammages are available
- Available Colours: White / Blue
- Available size: Customisation is available



DISPOSABLE BEDSHEET SET

- Includes: Pillow case, Blanket case and Bedsheet).
- Material: Various are available (PP, SMS, Laminated or Non-Laminated)
- Various grammages are available
- Available Colours: White / Blue
- Available size: Customisation is available

- All products can be customised due to special customer requests.
- Ultrasonic sealing is available upon request
- If you have any product request different than our product list, please kindly advise us your request and we will inform you about our abilities for production.
- Please feel free to contact for any enquiry or assistance.





SERTİFİKA / CERTIFICATE

SENMED MEDİKAL LİMİTED ŞİRKETİ

ZEYTİNLİ MAH. 79006 SK. NO: 3/8 ŞEHİTKAMİL / GAZİANTEP / TURKEY

Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

Has been assessed and found to Comply with the Requirements of:

ISO 9001:2015

QUALITY MANAGEMENT SYSTEM

KALİTE YÖNETİM SİSTEMİ

For scope “**PRODUCTION, SALES, AND EXPORT OF ALL TYPES OF STERILE AND NONSTERILE MEDICAL DEVICES, SURGICAL DEVICES, HOSPITAL EQUIPMENT AND MEDICAL TEXTILE PRODUCTS**”

Kuruluşunun “**STERİL VE STERİL OLMAYAN TIBBİ CİHAZLARIN, CERRAHİ CİHAZLARIN, HASTANE EKİPMANLARININ VE TIBBİ TEKSTİL ÜRÜNLERİNİN ÜRETİMİ, SATIŞI VE İHRACATI**” Kapsamı için

Sertifika Numarası / Certificate Number
İlk Yayın Tarihi / Certificate Issue Date
Sertifika Geçerlilik Tarihi / Certificate Validity Date
Sertifika Periyodu / Certificate Period

: NVA-QM-210728-02
: 28.07.2022
: 28.07.2023
: 1 Yıl / 1 Year



NVA denetim yürütülmesinde gerekli itina ve yetkinlik göstermesine rağmen büyük ihmallerde dahil sorumluluk kabul etmeyecektir. Bu belgenin mülkiyet hakkı NVA aittir ve istenildiğinde iade edilmelidir.

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Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

Has been assessed and found to Comply with the Requirements of:

ISO 13485:2016

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM

TIBBİ CİHAZLAR KALİTE YÖNETİM SİSTEMİ

For scope “**PRODUCTION, SALES, AND EXPORT OF ALL TYPES OF STERILE AND NONSTERILE MEDICAL DEVICES, SURGICAL DEVICES, HOSPITAL EQUIPMENT AND MEDICAL TEXTILE PRODUCTS**”

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Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

Has been assessed and found to Comply with the Requirements of:

ISO 10002:2018

CUSTOMER SATISFACTION MANAGEMENT SYSTEM

MÜŞTERİ MEMNUNİYETİ YÖNETİM SİSTEMİ

For scope **"PRODUCTION, SALES, AND EXPORT OF ALL TYPES OF STERILE AND NONSTERILE MEDICAL DEVICES, SURGICAL DEVICES, HOSPITAL EQUIPMENT AND MEDICAL TEXTILE PRODUCTS"**

Kuruluşunun **"STERİL VE STERİL OLMAYAN TIBBİ CİHAZLARIN, CERRAHİ CİHAZLARIN, HASTANE EKİPMANLARININ VE TIBBİ TEKSTİL ÜRÜNLERİNİN ÜRETİMİ, SATIŞI VE İHRACATI"** Kapsamı için

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: NVA-CM-210728-02

: 28.07.2022

: 28.07.2023

: 1 Yıl / 1 Year



NVA denetim yürütülmesinde gerekli itina ve yetkinlik göstermesine rağmen büyük ihmallerde dahil sorumluluk kabul etmeyecektir. Bu belgenin mülkiyet hakkı NVA aittir ve istenildiğinde iade edilmelidir.

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Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

Has been assessed and found to Comply with the Requirements of:

ISO 14001:2015

ENVIRONMENTAL MANAGEMENT SYSTEM

ÇEVRE YÖNETİM SİSTEMİ

For scope “**PRODUCTION, SALES, AND EXPORT OF ALL TYPES OF STERILE AND NONSTERILE MEDICAL DEVICES, SURGICAL DEVICES, HOSPITAL EQUIPMENT AND MEDICAL TEXTILE PRODUCTS**”

Kuruluşunun “**STERİL VE STERİL OLMAYAN TIBBİ CİHAZLARIN, CERRAHİ CİHAZLARIN, HASTANE EKİPMANLARININ VE TIBBİ TEKSTİL ÜRÜNLERİNİN ÜRETİMİ, SATIŞI VE İHRACATI**” Kapsamı için

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: NVA-EM-210728-02
: 28.07.2022
: 28.07.2023
: 1 Yıl / 1 Year



NVA denetim yürütülmesinde gerekli itina ve yetkinlik göstermesine rağmen büyük ihtimallerde dahil sorumluluk kabul etmeyecektir. Bu belgenin mülkiyet hakkı NVA aittir ve istenildiğinde iade edilmelidir.

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Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

Has been assessed and found to Comply with the Requirements of:

ISO 31000:2018

RISK MANAGEMENT SYSTEM

KURUMSAL RİSK YÖNETİM SİSTEMİ

For scope "PRODUCTION, SALES, AND EXPORT OF ALL TYPES OF STERILE AND NONSTERILE MEDICAL DEVICES, SURGICAL DEVICES, HOSPITAL EQUIPMENT AND MEDICAL TEXTILE PRODUCTS"

Kuruluşunun "STERİL VE STERİL OLMAYAN TIBBİ CİHAZLARIN, CERRAHİ CİHAZLARIN, HASTANE EKİPMANLARININ VE TIBBİ TEKSTİL ÜRÜNLERİNİN ÜRETİMİ, SATIŞI VE İHRACATI" Kapsamı için

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: 28.07.2022
: 28.07.2023
: 1 Yıl / 1 Year



NVA denetim yürütülmesinde gerekli itina ve yetkinlik göstermesine rağmen büyük ihmallerde dahil sorumluluk kabul etmeyecektir. Bu belgenin mülkiyet hakkı NVA aittir ve istenildiğinde iade edilmelidir.

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Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

Has been assessed and found to Comply with the Requirements of:

ISO 45001:2018

OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM

İŞ SAĞLIĞI VE GÜVENLİĞİ YÖNETİM SİSTEMİ

For scope “**PRODUCTION, SALES, AND EXPORT OF ALL TYPES OF STERILE AND NONSTERILE
MEDICAL DEVICES, SURGICAL DEVICES, HOSPITAL EQUIPMENT AND MEDICAL TEXTILE PRODUCTS**”

Kuruluşunun “**STERİL VE STERİL OLMAYAN TIBBİ CİHAZLARIN, CERRAHİ CİHAZLARIN, HASTANE
EKİPMANLARININ VE TIBBİ TEKSTİL ÜRÜNLERİNİN ÜRETİMİ, SATIŞI VE İHRACATI**” **Kapsamı için**

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Sertifika Geçerlilik Tarihi / Certificate Validity Date
Sertifika Periyodu / Certificate Period

: NVA-OS-210728-02
: 28.07.2022
: 28.07.2023
: 1 Yıl / 1 Year



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Tel: +90 212 855 58 98 www.nvabelge.com info@nvabelge.com

DECLARATION OF CONFORMITY

Company Name : SENMED MEDIKAL LTD. STI

Adress : ZEYTINLI MAH. 79006 SK. NO: 3/8 SEHITKAMIL
GAZIANTEP, TURKEY

Product Name : Nonsterile Medical Bedsheet, 150x200 cm
Nonsterile Medical Bedsheet, 50x40 cm

Brand : SENMED MEDICAL

GMDN No : It is in the appendix

Basic UDI-DI: : It is in the appendix

Classification : Class I-Other (Nonsterile)

Directive : 2017/745 (Medical Device Regulation)

Conformity Assesment : 2017/745 Medical Device Regulation Annex IV

We herewith declare that the products comply with the provisions of the Medical Device Regulation 2017/745 for medical devices. All supporting documentation is retained under the premises of the manufacturer. We declare that our products do not contain human blood, animal skin or products derived from these.

Harmonized Standards : EN ISO 13485:2016, EN ISO 15223-1:2013, EN ISO 14971:2012,
EN 1041:2011, EN ISO 14155-1:2012, EN ISO 13795+A1:2013,
EN ISO 10993-1:2011

ISO 13485 Certificate No : NVA-MD-210728-02
ISO 13485 Issue Date : 28.07.2022
ISO 13485 Expiry Date : 28.07.2023

Place : GAZIANTEP, TURKEY
Date : 05.09.2022

General Manager

SENMED MEDIKAL LTD. STI.
Zeytinli Mah. 79006 Sk. Korkmaz Tower No.3/8
Tel.: +90.544 797 48 72 - Şehitkamil/GAZIANTEP
Tic.Sic.No.59330 Mersis No.0761097672400001
Şehitkamil M.D. 761 097 6724

Appendix – List

PRODUCT	REF CODE	GMDN	BASIC UDI-DI
Nonsterile Medical Bedsheet, 150x200 cm	22681	47783	86836908965226814Y
Nonsterile Medical Bedsheet, 50x40 cm	22682	47783	868369089652268252

Place : GAZIANTEP, TURKEY

Date : 05.09.2022

General Manager

SENMED MEDİKAL LTD.ŞTİ.
Zeytinli Mah. 79006 Sk. Korkmaz Tower No.3/B
Tel.: +90.544 707 48 72 - Şehitkamil/GAZİANTEP
Tic.Sic.No.59330 Mersis No.0761097672400001
Şehitkamil V.D. 761 097 6724

DECLARATION OF CONFORMITY

Company Name : SENMED MEDIKAL LTD. STI
Adress : ZEYTINLI MAH. 79006 SK. NO: 3/8 SEHITKAMIL
GAZIANTEP, TURKEY
Product Name : Disposable Nonsterile Medical Gown, Sizes: S – M – L – XL – XXL – 3XL
Brand : SENMED MEDICAL
GMDN No : It is in the appendix
Basic UDI-DI: : It is in the appendix
Classification : Class I-Other (Nonsterile)
Directive : 2017/745 (Medical Device Regulation)
Conformity Assesment : 2017/745 Medical Device Regulation Annex IV

We herewith declare that the products comply with the provisions of the Medical Device Regulation 2017/745 for medical devices. All supporting documentation is retained under the premises of the manufacturer. We declare that our products do not contain human blood, animal skin or products derived from these.

Harmonized Standards : EN ISO 13485:2016, EN ISO 15223-1:2013, EN ISO 14971:2012,
EN 1041:2011, EN ISO 14155-1:2012, EN ISO 13795+A1:2013,
EN ISO 10993-1:2011

ISO 13485 Certificate No : NVA-MD-210728-02
ISO 13485 Issue Date : 28.07.2022
ISO 13485 Expiry Date : 28.07.2023

Place : GAZIANTEP, TURKEY
Date : 05.09.2022

General Manager

SENMED MEDIKAL LTD. STI.
Zeytinli Mah. 79006 Sk. Kocimen Tower No.3/8
Tel.: +90.544 797 48 72 - Sehitkamil/GAZIANTEP
Tic.Sic.No.59330 Mersis No.0761097672400001
Sehitkamil V.D. 761 097 6724

Appendix – List

PRODUCT	REF CODE	GMDN	BASIC UDI-DI
Disposable Nonsterile Medical Gown, Sizes: S	22683	35092	868369089652268354
Disposable Nonsterile Medical Gown, Sizes: M	22684	35092	868369089652268456
Disposable Nonsterile Medical Gown, Sizes: L	22685	35092	868369089652268558
Disposable Nonsterile Medical Gown, Sizes: XL	22686	35092	86836908965226865A
Disposable Nonsterile Medical Gown, Sizes: XXL	22687	35092	86836908965226875C
Disposable Nonsterile Medical Gown, Sizes: 3XL	22688	35092	86836908965226885E

Place : GAZIANTEP, TURKEY

Date : 05.09.2022

General Manager

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