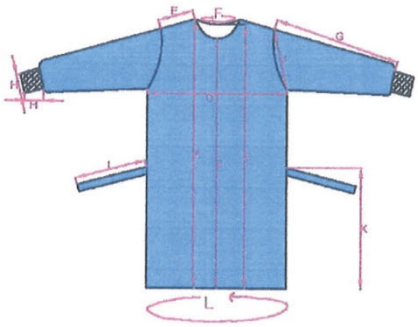
medivendo by medical GROUP

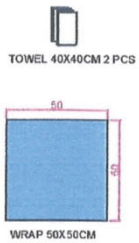
MEDIVENDO SWISS

Product Performance according to EN 13795:2011+A1:2013 (tests performed after sterilization)

Characteristic	Standard	Unit	Requirement Product Performance		Product values	
			Less Critical area	Critical area	Less Critical area	Critical area
Resistance to microbial penetration - Dry	EN ISO 22612:203005	CFU	≤300	Not required	4	NR
Resistance to microbial penetration - Wet	EN ISO 22610:2006	I_B	Not required	6,0	NR	6,0
Cleanliness - Microbial	EN ISO 11737-1:2006	CFU/100cm²	≤300	≤300	15	15
Cleanliness – Particulate matter	EN ISO 9073-10: 2004	IPM	≤3,5	≤3,5	2,7	2,7
Linting	EN ISO 9073-10: 2004	Log_{10} (lint count)	4,0≤	4,0≤	3,2	3,2
Resistance to liquid penetration	EN 20811:1992	cm H_2O	≥10	≥100	43	43
Bursting strength - Dry	EN ISO 13938-1: 2002	kPa	≥40	≥40	196	196
Bursting strength - Wet	EN ISO 13938-1: 2002	kPa	Not required	≥40	187	187
Tensile strength - Dry	EN 29073-3: 1992	N	≥20	≥20	MD:92,8 CD:44,6	MD:92,8 CD:44,6
Tensile strength - Wet	EN 29073-3: 1992	N	Not required	≥20	MD:92,1 CD:42,4	MD:92,1 CD:42,4

Product fulfill product performance requirements for critical product area.





	S	M	L	XL	XXL	
REF NO.	0001	0002	0003	0004	0005	TOL.
A	112	115	123	135	148	(+-3)
B	104.5	107.5	115	126.5	139.5	(+-3)
C	109	112	119.5	131	143	(+-3)
D	61	63	66	70	73	(+-3)
E	17.5	18	19.5	21	22.5	(+-3)
F	65.5	68	72	72	74	(+-3)
G	57	58	59	60	63	(+-3)
H	10 / 7	10 / 7	10 / 7	10 / 7	10 / 7	(+-3)
I	70	70	70	70	70	(+-3)
J	56.5	58	59	60	60.5	(+-3)
K	63.5	66	73	84	96	(+-3)
L	142	146	153	160	167	(+-3)

Falammability 16 CFR 1610 Class 1

Instruction Intended Use

Surgical drapes, when sterilized, are intended to minimize the spread of microorganisms in order to reduce the risk for post-operative wound infection. Before use needs to be sterilized by ETO method.

CE Mark Certificate

Class I, rule 1

For non-sterile, non-measuring class I products there are no Notified Body Certificate

Instruction Storage

We recommend that products are stored under normal storage Conditions. Protect against sunlight. All layers of packing should be kept intact until Acceyss to the underlying layers is needed

Instruction Disposable Waste

Non-hazardous waste used products should, in the majority of cases, be Classified as non-hazardous waste. They contain high amounts of energy and are well suited for incineraion. Products do not contain any hazardous substances that can leach out if the products are land filled. Transport boxes are designed to fit existing recovery systems

Standard SMS Gown
CE Zertifikat

UDEM

CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name :

Company Address :

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 :
Report Number :
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.

UDEM

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

medivendo by MWM medical GROUP

MEDIVENDO SWISS

Standard SMS Gown
ISO 9001 : 2015

PCA
PARTNERS CERTIFICATE ASSURANCE

Certificate

ISO 9001 : 2015

This certificate shows that the quality management system of the above company was approved by PCA Sertifikasyon for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria.

SCOPE

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

EA CODE

23

Certificate No	:
Registration Date	: 05.12.2017
Reissue Date	: 03.12.2018
Expiry Date	: 04.12.2019
Certificate Period	: 3 Years (From the date of registration)
Exclusion	:

IAS ACCREDITED
Management Systems Certification Body
MSCB-103

PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49
www.pca-tr.com info@pca-tr.com

FR.86 Rev.4

medivendo by MUM medical GROUP

MEDIVENDO SWISS

Standard SMS Gown
ISO 13485 : 2016

akssert

CERTIFICATE

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 :
Registration Date : 05.12.2017

Reissue Date : 03.12.2018
Expiry Date : 04.12.2020

Adres: Mustafa Kemal Mah. 2157/1 Sokak No:5/3 Çankaya / ANKARA– TÜRKİYE
Tel: +90 312 219 82 92 (pbx) **Faks:** +90 312 219 42 32
E-posta: info@akssert.com **Web:** www.akssert.com

Standard SMS Gown
EN 13795+A1

TÜRK STANDARDLARI ENSTİTÜSÜ

TÜRK STANDARDLARINA UYGUNLUK BELGESİ

TURKISH STANDARDS INSTITUTION

CERTIFICATE OF CONFORMITY TO TURKISH STANDARDS

Markanın Tanımı / Description of the Mark

TSE

BELGE NUMARASI
REFERENCE NUMBER OF LICENCE

BELGENİN İLK VERİLİŞ TARİHİ 27.04.2007
DATE OF FIRST ISSUE OF LICENCE

BELGENİN SON GEÇERLİLİK TARİHİ 30.03.2021
LICENCE VALID UNTIL

BELGE SAHİBİ KURULUŞUN ADI
NAME OF THE LICENCE HOLDER

BELGE SAHİBİ KURULUŞUN ADRESİ
ADRESS OF THE LICENCE HOLDER

ÜRETİM YERİ ADI
NAME OF THE MANUFACTURING PLACE

ÜRETİM YERİ ADRESİ
ADRESS OF THE MANUFACTURING PLACE

İPTAL EDİLEN BELGE NUMARASI (Varsa)
INDICATION OF SUPERSEDED LICENCE (if any)

TESCİLLİ TİCARİ MARKASI
REGISTERED TRADE MARK

İLGİLİ TÜRK STANDARDI TS EN 13795+A1 / 12.06.2013
RELATED TURKISH STANDARD

BELGE KAPSAMI
SCOPE OF LICENCE

HASTALAR, KLİNİK PERSONELİ VE DONANIMLAR İÇİN TIBBİ CİHAZ OLARAK KULLANILAN
CERRAHİ ÖRTÜ-YÜKSEK PERFORMANS,TEK KULLANIMLIK
CERRAHİ ÖRTÜ-STANDARD PERFORMANS,TEK KULLANIMLIK
CERRAHİ ÖNLÜK-YÜKSEK PERFORMANS,TEK KULLANIMLIK
CERRAHİ ÖNLÜK-STANDARD PERFORMANS,TEK KULLANIMLIK

Bu belge belgelendirilen ürünün üretim yerinin Enstitümüzün belirlediği şartları karşıladığını da gösterir.
Bu belge hiç bir suretle tanıtım edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
TSE BURSA BELGELENDİRME MÜDÜRLÜĞÜ Adres: Organize Sanayi Bölgesi Kırmızı Cad. No:6 16140 BURSA Telefon: 0224243800/5H Faks: 0224243824
TSE BELGELENDİRME MERKEZ BAŞKANLIĞI Adres: Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA Telefon: 0 312 416 64 31 - 416 64 37 Faks: 0 312 416 66 17 E-posta: bmo@tse.org.tr web: www.tse.org.tr