EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

AB-0583-T
21012425-ing
04-21

Customer name:	BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. AŞ.
Address:	ORGANİZE SANAYİ BÖLG.19 NO'LU CAD.NO:11 MERKEZ/KİLİS
Buyer name:	-
Contact Person:	KADİR KARAGÜN
Order No:	REF:SD-04210-18/LOT:0000016139
Article No:	REINFORCED SURGICAL CLOTH(HIGH PERFORMANCE)
Name and identity of test item:	One sample blue surgical gown.(Claimed to be;4 Pieces Color:Medikal Blue)
The date of receipt of test item:	12.04.2021
Re-submitted/re-confirmation date:	-
Date of test:	12.04.2021-26.04.2021
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	
Number of pages of the report:	9

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.
The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
TESTED BY EKOTEKS TEST EDİLMİŞTİR	26.04.2021	Yeşim ŞAHİN	Sevim A. RAZAK 26.04.2021

Digitally signed by Granaci Boris
Date: 2022.09.13 12:07:53 EEST
Reason: MoldSign Signature
Location: Moldova

AB-0583-T
21012425-ing
04-21

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Resistance to Bacterial Penetration-Wet Method	P	
Resistance to Microbial Penetration-Dry Method	P	
PHYSICAL PROPERTIES TESTS		
Tensile Stregth / **Dry**	P	
Tensile Stregth / **Wet**	P	
Bursting Strength / **Dry**	P	
Bursting Strength / **Wet**	P	
Water Permeability	P	
Blood Splash Resistance	P	
Lint And Other Particles Generation From Nonwoven	P	
P: Pass F: Fail R: Refer to retailer technologist. Test results were evaluated according to EN 13795-1:2019(*) High Performance Properties Critical Sample Group limit values (Table 1)		

Gen.f136-2/03

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified.If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. Tests marked (*) in this report are not included in the accreditation schedule

AB-0583-T
21012425-ing
04-21

TEST RESULTS

MICROBIAL CLEANLINESS (Bioburden) ; EN ISO 11737-1:2018

The sample is put in extraciton liquid after shaking well after shaking well (250 rpm,5 min), inoculated on the suitable agar.The plates are incubated for 3 days at 30 ± 1 ° C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively.
Total microoragnisms counts are calculated.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/100 cm^2)	7 cfu/100 cm^2	≤300 cfu/100 cm^2

*cfu= Colony forming unit.

AB-0583-T
21012425-ing
04-21

TEST RESULTS

RESISTANCE TO BACTERIAL PENETRATION-WET METHOD ;
BS EN ISO 22610: 2006

A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are placed on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force (3N ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	$5x10^3$ kob/ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X_1	**0**	**RCUM1**	**0**
X_2	**0**	**RCUM2**	**0**
X_3	**0**	**RCUM3**	**0**
X_4	**0**	**RCUM4**	**0**
X_5	**0**	**RCUM5**	**0**
Z	**462**		
T	**462**		

X_1 ..... X_5: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: $X_1 + X_2 + X_3 + X_4 + X_5 + Z$

$R_{CUM1} = X_1/T$
$R_{CUM2} = (X_2 + X_1)/T$
$R_{CUM3} = (X_3 + X_2 + X_1)/T$
$R_{CUM4} = (X_4 + X_3 + X_2 + X_1)/T$
$R_{CUM5} = (X5 + X_4 + X_3 + X_2 + X_1)/T$

BARRIER INDEX (I_B)		
	Result	**Expected value (*)**
I_B	6	≥6

$I_B = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$

Gen.f136-2/03

AB-0583-T
21012425-ing
04-21

TEST RESULTS

RESISTANCE TO MICROBIAL PENETRATION-DRY METHOD; ISO 22612:2005

Samples and containers are sterilized. Agar plates are placed in each container. Samples are placed aseptically in the apparatus. The covers are closed. After making a pot in the sample with the piston, the pistons are removed and 0.5 g ± 0.1 g are added to five samples from the powder contaminated with bacteria and the six to the non-contaminated powder. Then all openings are closed with a plastic bag. The device is operated to give 20,800 vibrations per minute. The test time is 30 minutes. After the test is over, all agar plates are incubated at 35 ° C for 24 hours.

Sample amount:	6 pieces 20x20 cm^2
Mikroorganism:	*Bacillus subtilis ATCC 9372*
Bacterial concentration (cfu/ml):	$1x10^8$ kob/ml
Incubation conditions:	35°C / 24 hours

RESULTS

Number of Populationg Bacteria (cfu)	
1	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	-

RESULT

Result (cfu/g)	**Expected Value**
0 cfu/g	≤300 cfu/g

AB-0583-T
21012425-ing
04-21

TEST RESULTS

TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 5 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. Without wetting samples.
The average results are given for width and length direction of three samples
Performed in the conditioned room (20±2°C-65%±4).
Dry ;

	RESULT	REQUIREMENT
Width	151.1 N	≥ 20N (Dry)
Length	149.9 N	≥ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 5 kN), Strip Method.
Speed: 100 mm/min±10, Gauge length 200 mm.
Pre-load was not applied. Without wetting samples.
The average results are given for width and length direction of three samples
Performed in the conditioned room (20±2°C-65%±4).
Wet;

	RESULT	REQUIREMENT
Width	149.3 N	≥ 20N (Wet)
Length	154.6 N	≥ 20N (Wet)

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
The average results are given of 3 samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Dry ;	310.6 kPa	≥ 40 kPa (Dry)
Height at Burst*	10.4 mm	

AB-0583-T
21012425-ing
04-21

TEST RESULTS

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
The average results are given of 3 samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Wet ;	332.0 kPa	≥ 40 kPa (Wet)
Height at Burst*	12.4 mm	

WATER PERMEABILITY; ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model
Temperature of water 20°C. Pressure increase ratio 10 mbar/min.
Performed in the conditioned room (20±2°C-65%±4)

	RESULT	REQUIREMENT
Sample 1	555.9 cm H_2O	≥ 100 cm H_2O
Sample 2	587.5 cm H_2O	
Sample 3	562.0 cm H_2O	
Sample 4	560.0 cm H_2O	
Sample 5	578.3 cm H_2O	
Average	568.7 cm H_2O	

AB-0583-T
21012425-ing
04-21

TEST RESULTS

DETERMINATION OF THE RESISTANCE TO PENETRATION BY BLOOD AND BODY FLUIDS-USING SYNTHETIC BLOOD; ISO 16603:2004

Textest, FX 3000-IV model + External Blood Cell
Test samples were conditioned at 60 ± 10% relative humidity and 21 ± 5 ° C for at least 24 hours before testing.

Test Procedure Applied: A procedure
B procedure (Only extensible or elastomeric materials)

Pressure (kPa)	Time (Min.)	Test Result			Overall Result
		Test 1	Test 2	Test 3	
0	5	PASS	PASS	PASS	PASS
14	1	PASS	PASS	PASS	
0	4	PASS	PASS	PASS	
The time of failure (sn)		-	-	-	
Thickness of material tested (mm):		0.61	0.61	0.61	
Weight of material tested (g/m²) :		0.88	0.88	0.88	

AB-0583-T
21012425-ing
04-21

TEST RESULTS

LINT AND OTHER PARTICLES GENERATION FROM NONWOVEN; ISO 9073-10: 2003

5 samples in longitudinal direction (separate for inner and outer surface) are tested. The samples are placed in the Gelbo Flex device, which makes twisting and compression movements, in a clean room in Class 5 category according to ISO 14644-1. Lint and particles detached from the sample are counted with counter device and classified to size range.

SOLAIR 3100 particles measuring device
Min. measuring size: 0,3 µm,
Maks. measuring size: 25 µm
Air Flow: : 28,3 ± 1,4 L/dk
Working mode: 30 sec x 10 consecutive periods

SAMPLE (INNER SURFACE)		SAMPLE (OUTER SURFACE)	
Total linting :	86	Total linting :	26
Standard deviation :	50	Standard deviation :	20
Coefficient of variation :	%58	Coefficient of variation :	%78
Coefficient of linting (CL):	2	Coefficient of linting (CL):	1

SAMPLE (TOTAL)	
Total linting :	112
Coefficient of linting (CL)*	2

* According to EN ISO EN ISO 13795-1:2019, Coefficient of linting (CL) (log 10) should be ≤4 for analysis of critical product area and less critical product area of both standard performance and high performance testing.

Gen.f136-2/03

DATE	09.08.2022
DOC.NO	MF69
PAGE NO	1
REV.NO	
REV.DATE	

TECHNICAL DATA SHEET

PRODUCT: **Sterile Surgical Set For Laborious (long-term) Interventions SP-03007-89**

Description of Product:

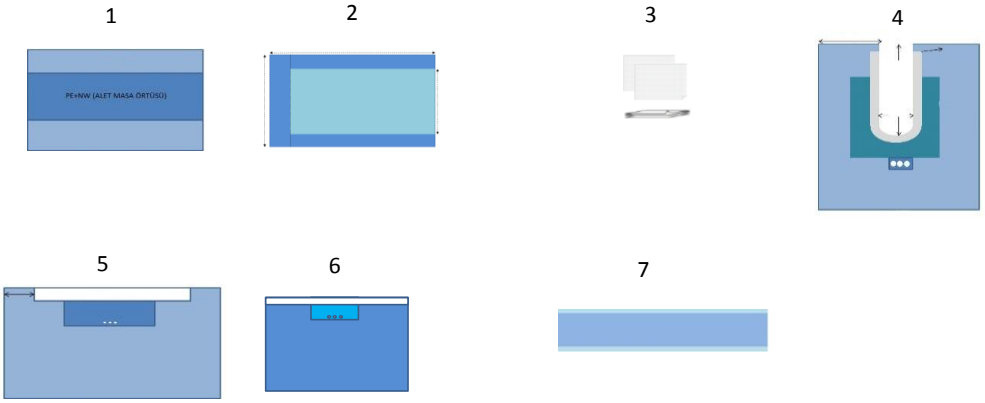
Sterile Surgical Set For Laborious (long-term) Interventions			
1	Instrument Table Cover	150x190 cm +-10	1
2	Mayo Stand Cover	80x140 cm +-10	1
3	Towel	40x40 cm	2
4	U Split Drape	200x310 cm	1
5	Anesthesia Drape	150x270 cm	1
6	Side Adhesive Drape	95x105 cm	2
7	Op-Tape	10x50 cm	1

Raw Materials:	PE+Nw / Cellulose / Sms+Reinforced
Product Colour:	Medical Blue
Reference Code:	
Weight in Grams:	35 gsm(Sms)+Reinforced / 60 gsm(Cellulose) / 43 gsm(Sms)+Reinforced
Package:	Flat Pouch

Product: MDD Manufactured in accordance with 93/42 / EEC Annex / IX requirements. Products and materials used do not contain metal.

Product Materials		Unit / Size
1	PE+Nw	150x190 cm +-10
2	PE+Nw	80x140 cm +-10
3	Cellulose	40x40 cm
4	Sms + Reinforced	200x310 cm
5	Sms + Reinforced	150x270 cm
6	Sms + Reinforced	95x105 cm
7	***	10x50 cm

PROPERTIES



Tolerances: **+/- 2% cm**

Measurement: **cm**

Package Information

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into Baymed's standard sized carton; dimensions are as follows:
Height = 44 cm; Length = 40 cm ve Width = 60 cm.

Preparation Date	QUALİTY CONTROL APPROVAL

DATE	09.08.2022
DOC.NO	MF69
PAGE NO	1
REV.NO	
REV.DATE	

TECHNICAL DATA SHEET

PRODUCT: **Sterile Universal Pack SP-03007-43**

Description of Product:

Sterile Universal Pack			
1	Instrument Table Cover , PE+Nw	150x190 cm	1
2	Mayo Stand Cover , PE+Nw	80x140 cm	1
3	Towel , Cellulose	40x40 cm	2
4	Foot Drape , Sms+Reinforced	190x195 cm +-10	1
5	Anesthesia Drape , Sms+Reinforced	150x270 cm	1
6	Op-Tape	10x50 cm	1

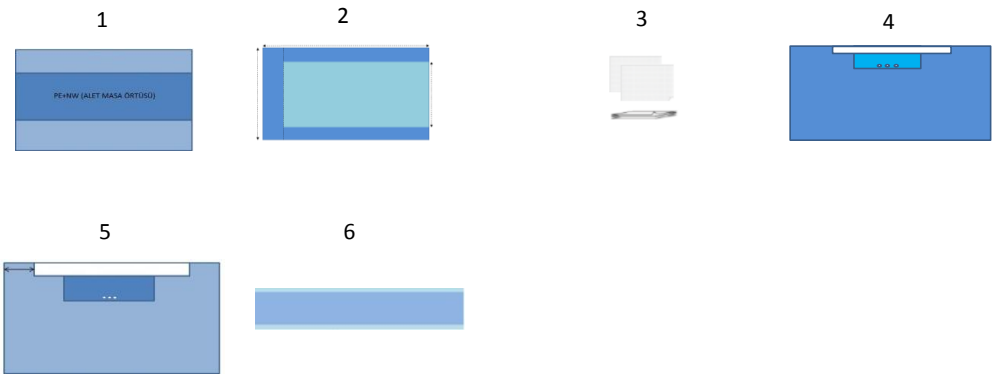
Raw Materials:	Sms+Reinforced/ PE+Nw / Cellulose
Product Colour:	Medical Blue
Reference Code:	
Weight in Grams:	43 gsm(Sms)+Reinforced / 35 gsm(Sms)+60 mic(PE) / 60 gsm(Cellulose)
Package:	Flat Pouch

Product: MDD Manufactured in accordance with 93/42 / EEC Annex / IX requirements. Products and materials used do not contain metal.

Product Materials

Unit / Size		
1	PE+Nw	150x190 cm
2	PE+Nw	80x140 cm
3	Cellulose	40x40 cm
4	Sms + Reinforced	190x195 cm +-10
5	Sms + Reinforced	150x270 cm
6	***	10x50 cm

PROPERTIES



Tolerances: **+/- 2% cm**

Measurement: **cm**

Package Information

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into Baymed's standard sized carton; dimensions are as follows:
Height = 44 cm; Length = 40 cm ve Width = 60 cm.

Preparation Date	QUALİTY CONTROL APPROVAL

DATE	09.08.2022
DOC.NO	MF69
PAGE NO	1
REV.NO	
REV.DATE	

TECHNICAL DATA SHEET

PRODUCT: **Sterile Birth Pack SP-03007-34**

Description of Product:

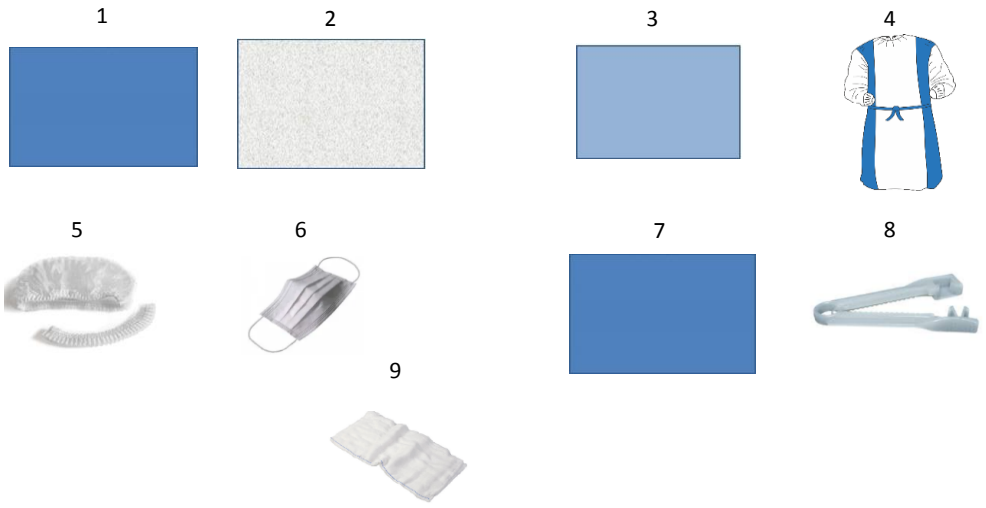
Sterile Birth Pack			
1	laminated sheet 2. size: 100 X 75 cm 3. 1 piece	100x75 cm	1
2	dense absorbent pads 2.size 80 X 70 cm (+/-5 cm) 3.4 pieces	80x70 cm +-5	4
3	diaper (protective) 2. size: 90 X 60 cm 3.1 piece	90x60 cm	1
4	laminated apron 2.1 pcs	St	1
5	bonnet 2.1 piece	St	1
6	surgical mask 2. three layers with elastic 3. 1 piece	St	1
7	1.sheet 2.material: SMS 3.size: 130 X 75 cm 4.1 piece	130x75 cm	1
8	umbilical cam 2. 1 piece	St	1
9	mini roll of cotton wool 2. 2 pcs.	St	2

Raw Materials:	Biflex / Sms+Reinforced / Spunlace / Sms
Product Colour:	Medical Blue
Reference Code:	
Weight in Grams:	56 gsm(Biflex) / 35 gsm(Sms)+Reinforced / 67,8 gsm(Spunlace) / 43 gsm (Sms)
Package:	Flat Pouch

Product: MDD Manufactured in accordance with 93/42 / EEC Annex / IX requirements. Products and materials used do not contain metal.

Product Materials		
Unit / Size		
1	Biflex	100x75 cm
2	Spunlace	80x70 cm +-5
3	Biflex	90x60 cm
4	Sms + Reinforced	L
5	***	St
6	***	St
7	Sms	130x75 cm
8	***	St
9	***	St

PROPERTIES



Tolerances: **+/- 2% cm**

Measurement: **cm**

Package Information

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into Baymed's standard sized carton; dimensions are as follows:
Height = 44 cm; Length = 40 cm ve Width = 60 cm.

Preparation Date	QUALİTY CONTROL APPROVAL

DATE	09.08.2022
DOC.NO	MF69
PAGE NO	1
REV.NO	
REV.DATE	

TECHNICAL DATA SHEET

PRODUCT: **Sterile Cesarean Section Pack SP-03007-21**

Description of Product:

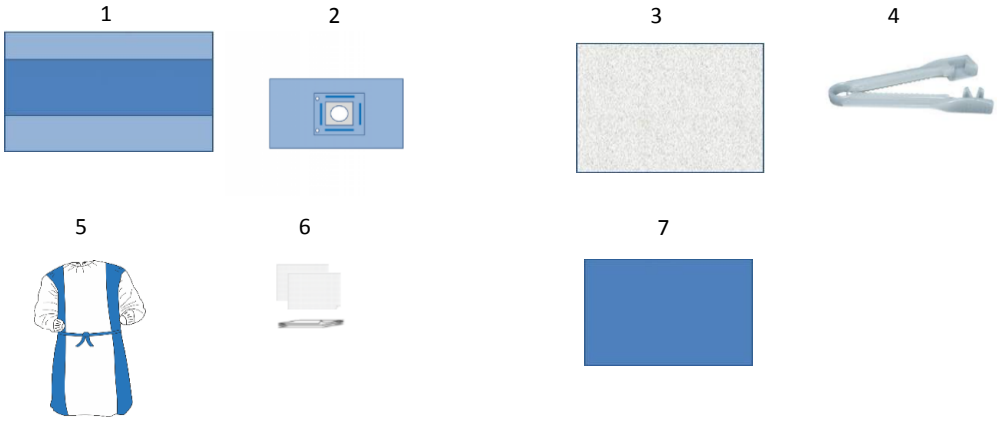
Sterile Cesarean Section Pack			
1	sheet for the instrument table	150x200 cm	1
2	sheet for caesarean section with collector pocket 2. size: ~ 200 x 300 cm - 1 pc.	200x300 cm	1
3	1. sheet for newborn 2. size: ~ 75 x 90 cm. 1 pc	75x90 cm	1
4	umbilical clip - 1 pc.	St	1
5	surgical gown (SMS material) reinforced 2. size: L (universal) - 2 pcs.	L	2
6	hand towel 2. size: 40 x 40 cm - 2 pcs.	40x40 cm	2
7	sheet 2. size: 100 x 100 cm - 1 pc.	100x100 cm	1

Raw Materials:	Sms+Reinforced / PE+Nw / Spunlace / Cellulose / Sms
Product Colour:	Medical Blue
Reference Code:	
Weight in Grams:	35 gsm(Sms)+Reinforced/67,8 gsm(Spunlace)/43 gsm (Sms)/35 gsm(Sms)+60 mic(PE)/60 gsm(Cellulose)
Package:	Flat Pouch

Product: MDD Manufactured in accordance with 93/42 / EEC Annex / IX requirements. Products and materials used do not contain metal.

Product Materials		Unit / Size
1	PE+Nw	150x200 cm
2	Sms	200x300 cm
3	Spunlace	75x90 cm
4	***	St
5	Sms + Reinforced	L
6	Cellulose	40x40 cm
7	Sms	100x100 cm

PROPERTIES



Tolerances: **+/- 2% cm**

Measurement: **cm**

Package Information

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into Baymed's standard sized carton; dimensions are as follows:
Height = 44 cm; Length = 40 cm ve Width = 60 cm.

Preparation Date	QUALİTY CONTROL APPROVAL