

Către Agenția Medicamentului și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. din

Solicitantul **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**, tel./fax: **022 782 875**, e-mail: **irina.sandu@dita.md** solicit
înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri
de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a
producătorului **Podima Medikal ve Tekstil San.Tic. Ltd. Sti, Turcia:**

- Boneta medicala (conform Anexei 3)
- Bahile (conform Anexei 3)
- Combinezon Tip 5-B, Tip 6-B (conform Anexei 3)
- Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B (conform Anexei 3)
- Halat Nesteril Set (conform Anexei 3)
- Mască medical (conform Anexei 3)
- Halat Nesteril din material (conform Anexei 3)
- Bahile inalte (conform Anexei 3)
- Halat nesteril material neșesut (conform Anexei 3)
- Halat Nesteril din material (conform Anexei 3)
- Cearșaf medical nesteril (conform Anexei 3)

Se anexează următoarele acte:

- Actul de reprezentanță între producător și reprezentantul autorizat în Republica Moldova;
- Declarația de conformitate CE;
- Declarația pe propria răspundere a solicitantului;
- Lista dispozitivelor medicale (format Excel).

Data **11.09.2023**

Semnătura



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	Nr. 7353 din 11.09.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Glaudea Diana Dionisie
Semnătura persoanei responsabile	CDJ

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032,**
Chisinau, Republica Moldova,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producătorului producătorului **Podima Medikal ve Tekstil San.Tic. Ltd. Sti, Turcia:**

- Boneta medicala (conform Anexei 3)
- Bahile (conform Anexei 3)
- Combinezon Tip 5-B, Tip 6-B (conform Anexei 3)
- Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B (conform Anexei 3)
- Halat Nesteril Set (conform Anexei 3)
- Mască medical (conform Anexei 3)
- Halat Nesteril din material (conform Anexei 3)
- Bahile inalte (conform Anexei 3)
- Halat nesteril material neșesut (conform Anexei 3)
- Halat Nesteril din material (conform Anexei 3)
- Cearșaf medical nesteril (conform Anexei 3)

Sunt autentice și corespund realității.

Numele, prenumele și funcția:

RA-Manager – Sandu Irina

Semnătura



Istanbul, Turkey
24.08.2022

We, Podima Medikal ve Tekstil San.Tic. Ltd. Sti, based in Şerifali Mah. Mevdudi Sok. No:53/1 34775 Ümraniye – İstanbul, assign **Dita Estfarm LLC**, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as **authorized representative** in correspondence with the conditions of Regulation (EU) 2017/745.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Istanbul, Türkiye

Date: 24.08.2022

Signed by: Mehmet Taşdemir
DIRECTOR

PODİMA MEDİKAL
VE TEKSTİL SAN.TİC.LTD.ŞTİ.
Serifali Mah. Mevdudi Sok.No:53/1
Ümraniye/İST. Tic.Sic.No: 889545-0
Sarıgazi V.D: 730 037 5548



**PODiMA**

M E D I K A L

(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of
PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE BONNETS – HAIR COVERS
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-40 – SV-41 – SV-42 – SV-43 – SV-44 – SV-45 – SV-46 – SV-47 – SV-48 – SV-49 – SV-50 – SV-51 – SV-52 – SV-53 – SV-54 – SV-55 – SV-56 – SV-57 – SV-58 – SV-59
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tesis for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE – SV-49: 868305212SV-49RBONNETC7 NON-STERILE – SV-50: 868305212SV-50OBONNET5Y NON-STERILE – SV-51: 868305212SV-51ABONNETSXA NON-STERILE – SV-52: 868305212SV-52BBONNETY6 NON-STERILE – SV-53: 868305212SV-53HBONNET42 NON-STERILE – SV-54: 868305212SV-54LBONNET6R NON-STERILE – SV-55: 868305212SV-55PEBONNET7V NON-STERILE – SV-56: 868305212SV-56RBBONNET87 NON-STERILE – SV-57: 868305212SV-57SABONNET8Y STERILE - SV-49: 868305212SV-49RBONNETSEB

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(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)

2017/745 Medical Devices Regulation / Class I

STERILE - SV-50: 868305212SV-50BONNETS6Y
STERILE - SV-51: 868305212SV-51ABONNETSXA
STERILE - SV-52: 868305212SV-52BBONNETSYL
STERILE - SV-53: 868305212SV-53HBONNETS4Y
STERILE - SV-54: 868305212SV-54LBONNETS83
STERILE - SV-55: 868305212SV-55PEBONNETS8D
STERILE - SV-56: 868305212SV-56RBBONNETS8X
STERILE - SV-57: 868305212SV-57SABONNETS9Y

We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Issue Date: 29.07.2022



Sign - Stamp

PODIMA MEDİKAL
VE TEKSTİL SANİTİ LTD.ŞTİ.
Serifali Mah.Mevdudu Sk.No:53/1
Umraniye/İST. Tlf. No: 889545-0
Sarıgazi V.D: 736 037 5548





(EU) 2017/745
DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of
PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE FOOT PROTECTIVE
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-60 – SV-61 – SV-62 – SV-63 – SV-64 – SV-65 – SV-66 – SV-67 – SV-68 – SV-69 – SV-70 – SV-71 – SV-72 – SV-73 – SV-74 – SV-75 – SV-76 – SV-77 – SV-78 – SV-79
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tesis for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE – SV-60: 868305212SV60PE9MICY9 NON-STERILE – SV-61: 868305212SV61PE20MICFY STERILE - SV-60: 868305212SV60PE9MICSPQ STERILE - SV-61: 868305212SV61PE20MICS6P





(EU) 2017/745
DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Issue Date: 28.07.2022



Sign - Stamp

PODiMA MEDİKAL
VE TEKSTİL SANİT. LTD. STİ.
Serifali Mah. Mevduidi / Sk. No: 53/1
Umraniye / İST. Tic. Sic. No: 889545-0
Sarıgezi V.D: 790 037 5548



**PODİMA**

M E D İ K A L

(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of
PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE COVERALL
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-100 – SV-101 – SV-102 – SV-103 – SV-104 – SV-105 – SV-106 – SV-107 – SV-108 – SV-109
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tests for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE - S to 4XL: 868305212SV-100SERIESCML STERILE - S to 4XL: 868305212SV-100SERIESCSHM

**EU DECLARATION OF CONFORMITY**www.podimamedikal.cominfo@podimamedikal.com



(EU) 2017/745
DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Issue Date: 28.07.2022



Sign - Stamp

PODiMA MEDİKAL
VE TEKSTİL SANİTİ LTD.ŞTİ.
Serifali Mah. Mevduci Sk. No: 53/1
Ümraniye/İST. Tic. Sic. No: 889545-0
Serigözi V.D: 792 037 5548



EU DECLARATION OF CONFORMITY

**PODİMA**

M E D İ K A L

(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of
PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE COVERALL
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-110 – SV-111 – SV-112 – SV-113 – SV-114 – SV-115 – SV-116 – SV-117 – SV-118 – SV-119
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tesis for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE - S to 4XL: 868305212SV-110SERIESCNB STERILE - S to 4XL: 868305212SV-110SERIESCSJJ

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(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Issue Date: 28.07.2022



Sign - Stamp

PODiMA MEDİKAL
VE TEKSTİL SANİT. LTD. STİ.
Serifali Mah. Mevduci Sk. No: 53/1
Ümraniye/İST. Tic. Sic. No: 889545-0
Serigazi V.D: 037 5548





(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of
PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE GOWN SET
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-120 – SV-121 – SV-122 – SV-123 – SV-124 – SV-125 – SV-126 – SV-127 – SV-128 – SV-129
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tesis for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE – SMS - S to 4XL: 868305212SV-120SMSGS4U NON-STERILE – SMMS - S to 4XL: 868305212SV-120SMMSGSS36 NON-STERILE – SMS - S to 4XL: 868305212SV-121SMSTS6G NON-STERILE - S to 4XL: 868305212SV-122TJLM NON-STERILE - S to 4XL: 868305212SV-128CPLC STERILE – SMS - S to 4XL: 868305212SV-120SMSGSSTQ STERILE – SMMS - S to 4XL: 868305212SV-120SMMSGSSU3 STERILE – SMS - S to 4XL: 868305212SV-121SMSTSSWA STERILE - S to 4XL: 868305212SV-122TJSW6





(EU) 2017/745
DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

STERILE - S to 4XL: 868305212SV-128CPSVD

We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Sign - Stamp

Issue Date: 20.02.2023



PODiMA MEDİKAL
VE TEKSTİL SANİT. LTD. STİ.
Serifali Mah. Mevduci Sk. No: 53/1
Ümraniye/İST. Tic. Sic. No: 889545-0
Serigazi V.D: 037 5548





(EU) 2017/745
DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of
PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE MASK – FFP2
SPECIFICATION:	NON-STERILE
ITEM NUMBERS:	SV-130 – SV-131 – SV-132 – SV-133 – SV-134 – SV-135 – SV-136 – SV-137 – SV-138 – SV-139 / Medium: SV-138-M - SV-139-M, Small: SV-136-S - SV-137-S
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 14683:2019+AC:2019 - Medical face Masks - Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tesis for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	SV-130 White - 868305212SV-130SERIESQC SV-131 Black - 868305212SV-131BD





(EU) 2017/745
DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Issue Date: 30.01.2023



Sign - Stamp

PODiMA MEDİKAL
VE TEKSTİL SANİTİ LTD.ŞTİ.
Serifali Mah.Mevduatı Sk.No:53/1
Umraniye/İST. Tic.Sic.No:889545-0
Serigazi V.D: 037 5548



**PODİMA**

M E D İ K A L

(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of
PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE GOWN
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-140 – SV-141 – SV-142 – SV-143 – SV-144 – SV-145 – SV-146 – SV-147 – SV-148 – SV-149
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tesis for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE – PP+PE - S to 4XL: 868305212SV-140SERIESQX NON-STERILE – PP+PE - 139X139: 868305212SV-140US139XB NON-STERILE – SMMS - S to 4XL: 868305212SV-141SMMSGS NON-STERILE – SMMS - 139X139: 868305212SV-141US139XQ NON-STERILE – SSMMS - S to 4XL: 868305212SV-142SSMMS7N NON-STERILE – SSMMLS - S to 4XL: 868305212SV-143SSMMLSXJ NON-STERILE – PP+PE - S to 4XL: 868305212SV-144PPPEH5T

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(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

NON-STERILE - SMMS+PE - S to 4XL: 868305212SV-144SMMSH72
NON-STERILE - SMS+PE - S to 4XL: 868305212SV-144SMSHHP
NON-STERILE - PP+PE - 139X139: 868305212SV-144HLAMUNISK3
NON-STERILE - PP+PE - 144X160: 868305212SV-144HLAMXLP9
NON-STERILE - S to 4XL: 868305212SV-145SMSXM
NON-STERILE - 139X139: 868305212SV-145US139ZC
STERILE - PP+PE - S to 4XL: 868305212SV-140STERILEU6
STERILE - PP+PE - 139X139: 868305212SV-140US139SK9
STERILE - SMMS - S to 4XL: 868305212SV-141SMMS6H
STERILE - SMMS - 139X139: 868305212SV-141US139SKS
STERILE - SSMMS - S to 4XL: 868305212SV-142SSMMS6H
STERILE - SSMMS - S to 4XL: 868305212SV-143SSMMS6H
STERILE - PP+PE - S to 4XL: 868305212SV-144PPPEHSUU
STERILE - SMMS+PE - S to 4XL: 868305212SV-144SMMSH72
STERILE - SMS+PE - S to 4XL: 868305212SV-144SMSH7M
STERILE - S to 4XL: 868305212SV-145SMSSJQ

We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Issue Date: 17.03.2023



Sign - Stamp

PODİMA MEDİKAL
VE TEKSTİL SANİT. LTD. STİ.
Serifali Mah. Mevduatı Sk. No: 53/1
Umraniye/İST. Tic. Sic. No: 889545-0
Serigazi V.D: 037 5548



**PODiMA**

M E D I K A L

(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of
PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE FOOT PROTECTIVE
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-150 – SV-151 – SV-152 – SV-153 – SV-154 – SV-155 – SV-156 – SV-157 – SV-158 – SV-159
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tesis for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE - S to 4XL: 868305212SV-150PPPEFPSX NON-STERILE - S to 4XL: 868305212SV-151PPPEFPTG STERILE - S to 4XL: 868305212SV-150PPPEFPSTD STERILE - S to 4XL: 868305212SV-151PPPEFPSTY

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(EU) 2017/745
DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Issue Date: 20.02.2023



Sign - Stamp

PODiMA MEDİKAL
VE TEKSTİL SANİTİ LTD. STİ.
Serifali Mah. Mevduatı St. No: 53/1
Umraniye/İST. Tic. Sic. No: 889545-0
Serigazi V.D: 78 037 5548



EU DECLARATION OF CONFORMITY

**PODİMA**

M E D İ K A L

(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

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PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE GOWN
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-180 – SV-181 – SV-182 – SV-183 – SV-184 – SV-185 – SV-186 – SV-187 – SV-188 – SV-189
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tests for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE – S to 4XL: 868305212SV-180SSGXQ NON-STERILE – 139X139: 868305212SV-180SSG139NY NON-STERILE – 120X140: 868305212SV-180SSG120NB STERILE – S to 4XL: 868305212SV-180SSGSJE

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(EU) 2017/745
DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

Issue Date: 20.02.2023

CEO of Company
MEHMET ALI OZKAN
Sign - Stamp



PODiMA MEDİKAL
VE TEKSTİL SAN. TİC. LTD. ŞTİ.
Serifali Mah. Mevduci Sk. No: 53/1
Ümraniye/İST. Tic. Sic. No: 889545-0
Sarıgezi V.D: 90 037 5548



**PODiMA**

M E D I K A L

(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

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PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODiMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE GOWN
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-190 – SV-191 – SV-192 – SV-193 – SV-194 – SV-195 – SV-196 – SV-197 – SV-198 – SV-199
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tesis for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE – PP+PE - S to 4XL: 868305212SV-190PPPEL74 NON-STERILE – PP+PE - S to 4XL: 868305212SV-191PPPEH79 NON-STERILE – PP+PE – 144X160: 868305212SV-191PPPEH144LP NON-STERILE – SMS+PE - S to 4XL: 868305212SV-191SMSPERYF NON-STERILE – SMMS+PE - S to 4XL: 868305212SV-191SSMSPER49 STERILE – PP+PE - S to 4XL: 868305212SV-190PPPELSW3 STERILE – PP+PE - S to 4XL: 868305212SV-191PPPELSW8 STERILE – SMS+PE - S to 4XL: 868305212SV-191SMSPERS2S

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(EU) 2017/745
DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

	STERILE – SMMS+PE - S to 4XL: 868305212SV-191SSMSPERS53
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We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Issue Date: 17.03.2023



Sign - Stamp

PODiMA MEDİKAL
VE TEKSTİL SANİTİ LTD.ŞTİ.
Serifali Mah. Mevduatı Sk. No: 53/1
Ümraniye/İST. Tic. Sic. No: 889545-0
Serigözi V.D: 037 5548



EU DECLARATION OF CONFORMITY

**PODİMA**

M E D İ K A L

(EU) 2017/745

DECLARATION OF CONFORMITY

in conformance to the European Economic Commission (EU)
2017/745 Medical Devices Regulation / Class I

This declaration of conformity is issued under the sole responsibility of
PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

MANUFACTURER:	PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. ŞERİFALİ MAH. MEVDUDİ SOK. NO: 53 İÇ KAPI NO: 1 ÜMRANIYE 34775 İSTANBUL / TURKEY
DESCRIPTION:	DISPOSABLE BED SHEETS – BED COVERS
SPECIFICATION:	NON-STERILE - STERILE
ITEM NUMBERS:	SV-600 – SV-601 – SV-602 – SV-603 – SV-604 – SV-605 – SV-606 – SV-607 – SV-608 – SV-609
TRADE MARK:	 SUVICOM
CLASS:	CLASS-I – (According to rule 1 ANNEX II-III-VIII)
ACTOR ID/SRN:	TR-MF-000028638
RELATED STANDARDS:	ISO 13485:2016 - Medical devices - Quality management systems. EN 13795-1:2019 - Surgical clothing and drapes. Requirements and test methods. EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices. EN ISO 10993 - Biological evaluation of medical devices. EN ISO 10993-1:2014 - Evaluation and testing within a risk management process. EN ISO 10993-2:2006 - Animal welfare requirements. EN ISO 10993-10:2014 - Tesis for irritation and skin sensitization. EN ISO 10993-12:2013 - Sample preparation and reference materials. EN ISO 10993-5:2010 - Tests for in vitro cytotoxicity.
BASIC UDI-DI NUMBERS:	NON-STERILE – 50X40: 868305212SV-600BS50X406X NON-STERILE – 200X150: 868305212SV-601B200150JV NON-STERILE – 90X240: 868305212SV-602B9024029 NON-STERILE – 90X220: 868305212SV-603B902202L NON-STERILE – 80X200: 868305212SV-606BS80X200VY NON-STERILE – 120X240: 868305212SV-606B120X240DB NON-STERILE – 80X200: 868305212SV-607BS80X24026

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DECLARATION OF CONFORMITY

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2017/745 Medical Devices Regulation / Class I

	NON-STERILE - 120X240: 868305212SV-607B120X240E4 STERILE - 50X40: 868305212SV-600BS50X406X STERILE - 200X150: 868305212SV-601B200150S3E
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We hereby declare that the abovementioned products meet the provisions of the medical devices regulation (EU) 2017/745. All supporting documentation is retained under the premises of the manufacturer. This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745.

CEO of Company
MEHMET ALI OZKAN

Issue Date: 28.07.2022



Sign - Stamp

PODIMA MEDİKAL
VE TEKSTİL SAN. TİC. LTD. ŞTİ.
Serifali Mah. Mevduat Sk. No: 53/1
Ümraniye/İST. Tic. Sic. No: 889545-0
Serigözi V.D: 037 5548



Anexa 3

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Boneta medicala	Suvicom	SV-40	
2		Boneta medicala	Suvicom	SV-41	
3		Boneta medicala	Suvicom	SV-42	
4		Boneta medicala	Suvicom	SV-43	
5		Boneta medicala	Suvicom	SV-44	
6		Boneta medicala	Suvicom	SV-45	
7		Boneta medicala	Suvicom	SV-46	
8		Boneta medicala	Suvicom	SV-47	
9		Boneta medicala	Suvicom	SV-48	
10		Boneta medicala	Suvicom	SV-49	
11		Boneta medicala	Suvicom	SV-50	
12		Boneta medicala	Suvicom	SV-51	
13		Boneta medicala	Suvicom	SV-52	
14		Boneta medicala	Suvicom	SV-53	
15		Boneta medicala	Suvicom	SV-54	
16		Boneta medicala	Suvicom	SV-55	
17		Boneta medicala	Suvicom	SV-56	
18		Boneta medicala	Suvicom	SV-57	
19		Boneta medicala	Suvicom	SV-58	
20		Boneta medicala	Suvicom	SV-59	
21		Bahile	Suvicom	SV-60	
22		Bahile	Suvicom	SV-61	
23		Bahile	Suvicom	SV-62	
24		Bahile	Suvicom	SV-63	
25		Bahile	Suvicom	SV-64	
26		Bahile	Suvicom	SV-65	
27		Bahile	Suvicom	SV-66	
28		Bahile	Suvicom	SV-67	
29		Bahile	Suvicom	SV-68	
30		Bahile	Suvicom	SV-69	
31		Bahile	Suvicom	SV-70	
32		Bahile	Suvicom	SV-71	
33		Bahile	Suvicom	SV-72	
34		Bahile	Suvicom	SV-73	
35		Bahile	Suvicom	SV-74	
36		Bahile	Suvicom	SV-75	
37		Bahile	Suvicom	SV-76	
38		Bahile	Suvicom	SV-77	
39		Bahile	Suvicom	SV-78	
40		Bahile	Suvicom	SV-79	
41		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-100	
42		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-101	
43		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-102	
44		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-103	
45		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-104	
46		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-105	
47		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-106	
48		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-107	
49		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-108	
50		Combinezon Tip 5-B, Tip 6-B	Suvicom	SV-109	
51		Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-110	
52		Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-111	
53		Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-112	



54	Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-113	
55	Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-114	
56	Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-115	
57	Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-116	
58	Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-117	
59	Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-118	
60	Combinezon Tip 3-B, Tip 4-B, Tip 5-B, Tip 6-B	Suvicom	SV-119	
61	Halat Nesteril Set	Suvicom	SV-120	
62	Halat Nesteril Set	Suvicom	SV-121	
63	Halat Nesteril Set	Suvicom	SV-122	
64	Halat Nesteril Set	Suvicom	SV-123	
65	Halat Nesteril Set	Suvicom	SV-124	
66	Halat Nesteril Set	Suvicom	SV-125	
67	Halat Nesteril Set	Suvicom	SV-126	
68	Halat Nesteril Set	Suvicom	SV-127	
69	Halat Nesteril Set	Suvicom	SV-128	
70	Halat Nesteril Set	Suvicom	SV-129	
71	Mască medicală	Suvicom	SV-130	
72	Mască medicală	Suvicom	SV-131	
73	Mască medicală	Suvicom	SV-132	
74	Mască medicală	Suvicom	SV-133	
75	Mască medicală	Suvicom	SV-134	
76	Mască medicală	Suvicom	SV-135	
77	Mască medicală	Suvicom	SV-136	
78	Mască medicală	Suvicom	SV-137	
79	Mască medicală	Suvicom	SV-138	
80	Mască medicală	Suvicom	SV-139	
81	Mască medicală	Suvicom	SV-138-M	
82	Mască medicală	Suvicom	SV-139-M	
83	Mască medicală	Suvicom	SV-136-S	
84	Mască medicală	Suvicom	SV-137-S	
85	Halat Nesteril din material	Suvicom	SV-140	
86	Halat Nesteril din material	Suvicom	SV-141	
87	Halat Nesteril din material	Suvicom	SV-142	
88	Halat Nesteril din material	Suvicom	SV-143	
89	Halat Nesteril din material	Suvicom	SV-144	
90	Halat Nesteril din material	Suvicom	SV-145	
91	Halat Nesteril din material	Suvicom	SV-146	
92	Halat Nesteril din material	Suvicom	SV-147	
93	Halat Nesteril din material	Suvicom	SV-148	
94	Halat Nesteril din material	Suvicom	SV-149	
95	Bahile inalte	Suvicom	SV-150	
96	Bahile inalte	Suvicom	SV-151	
97	Bahile inalte	Suvicom	SV-152	
98	Bahile inalte	Suvicom	SV-153	
99	Bahile inalte	Suvicom	SV-154	
100	Bahile inalte	Suvicom	SV-155	
101	Bahile inalte	Suvicom	SV-156	
102	Bahile inalte	Suvicom	SV-157	
103	Bahile inalte	Suvicom	SV-158	
104	Bahile inalte	Suvicom	SV-159	
105	Halat nesteril material neșesut	Suvicom	SV-180	
106	Halat nesteril material neșesut	Suvicom	SV-181	



107	Halat nesteril material neșesut	Suvicom	SV-182
108	Halat nesteril material neșesut	Suvicom	SV-183
109	Halat nesteril material neșesut	Suvicom	SV-184
110	Halat nesteril material neșesut	Suvicom	SV-185
111	Halat nesteril material neșesut	Suvicom	SV-186
112	Halat nesteril material neșesut	Suvicom	SV-187
113	Halat nesteril material neșesut	Suvicom	SV-188
114	Halat nesteril material neșesut	Suvicom	SV-189
115	Halat Nesteril din material	Suvicom	SV-190
116	Halat Nesteril din material	Suvicom	SV-191
117	Halat Nesteril din material	Suvicom	SV-192
118	Halat Nesteril din material	Suvicom	SV-193
119	Halat Nesteril din material	Suvicom	SV-194
120	Halat Nesteril din material	Suvicom	SV-195
121	Halat Nesteril din material	Suvicom	SV-196
122	Halat Nesteril din material	Suvicom	SV-197
123	Halat Nesteril din material	Suvicom	SV-198
124	Halat Nesteril din material	Suvicom	SV-199
125	Cearșaf medical nesteril	Suvicom	SV-600
126	Cearșaf medical nesteril	Suvicom	SV-601
127	Cearșaf medical nesteril	Suvicom	SV-602
128	Cearșaf medical nesteril	Suvicom	SV-603
129	Cearșaf medical nesteril	Suvicom	SV-604
130	Cearșaf medical nesteril	Suvicom	SV-605
131	Cearșaf medical nesteril	Suvicom	SV-606
132	Cearșaf medical nesteril	Suvicom	SV-607
133	Cearșaf medical nesteril	Suvicom	SV-608
134	Cearșaf medical nesteril	Suvicom	SV-609

