KIMESTA

Medical

1.01 / Ime artikla

ZAŠČITNA OBLEKA ZA ENKRATNO NUPORABO 30 gr Vodoodporna -Ne Sterilna- DG06

COD. EG5DP06

1.02 / Uvoznik
Kimesta d.o.o.

1.03 / Država porekla
Turčija

1.04 / CE certifikat
Na voljo na zahtevo

1.05 / Predvidena uporaba
Medicinski pripomoček razreda I

1.06 / Direktive
Direktiva 93/42/CE
Regulavija (EU) MDR 2017/745

1.07 / Standardi
ISO 13485:2016.

1.08 / REF št.
DG06

1.09 / RDM št.
2023091

1.10 / Tehnični podatki
Nesterilna obleka za enkratno uporabo. Izdelano iz netkanega materiala SS, vodoodbojno, iz enega kosa. Manšeta iz elastičnega ali raztegljivega bombažnega dresa. Bele barve.

1.11 / Priporočena uporaba
Medicinski sektor bolnišnic in laboratorijev

1.12 / Surovina
Netkani material SS 30 gr/m2

1.13 / Skladiščenje ter navodila za uporabo
Shranjujte pri temperaturi med -5° in 40°C
Shranjujte v suhem okolju
Ne izpostavljajte neposredno sončni svetlobii

Velikost	*Koda artikla*
S	EG5DP06S
M	EG5DP06M
L	EG5DP06L
XL	EG5DP06XL
XXL	EG5DP0XXL
3XL	EG5DP063XL

2.01/ Primarna embalaža

Količina	1 kos, 10 kosov, 50 kosov
Dimenzije	350x300mm
Teža – material	40 gr. – toplotno zapečaten najlon.

2.02 / Sekundarna embalaža

Količina	100 kosov
Dimenzije	60x40x40cm
Teža - material	12kg cca. – Valoviti karton
Paleta	80x120 h 240 – 24 kartonov

EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued un der the sole responsibility of the manufacturer **Dentapharma İlaç Medikal San ve Tic Ltd. Şti. , Kalaba Mah. Ahmet Vefik Paşa Cad. No:13/b Keçiören Ankara/TURKEY** hereby declaring the following product.

Product Description: Single-use Isolation/Visitor Gown
Material: 30 gr/m² SS Fabric (The product does not contain latex and Phthalates. It's Water-repellent.)
Model: DG06
EU Representative: N/A

European Union Regulations:

Medical Device Directive

Risk class of the device in accordance with Annex IX: Class 1, Rule 1

The model is/are in conformity with the provisions of Regulation (EU) 93/42/EEC including fulfilment of the applicable essential requirements set out in Annex 1, and with the Standard transposing the harmonised European Standard Number(s):

ISO 9001:2015
ISO 13485:2016

Conformity assessment procedure: N/A (self declaration)

Medical Device Regulation

Risk: Protection against minimal risk - prolonged contact with water that could occur in the medical environment.

The model is/are in conformity with the provisions of MDR (EU) 2017/745 including fulfilment of the applicable essential health and safety requirements set out in Annex l.

Conformity assessment procedure: Modul A set out in Annex IV of Regulation

Signed by Serkan DADAKOĞLU

CEO of Dentapharma Medical Co.

Date of Issue: 04.06.2021

DENTAPHARMA İLAÇ MEDİKAL GIDA SAN. ve TİC. LTD. ŞTİ.
Kalaba Mah. Ahmet Vefik Paşa Cad. 06120 No: 13/B
Tel: +90 312 359 00 50 Keçiören / ANKARA
www.dentapharma.com info@dentapharma.com
DIŞKAPI V.D. 060 047 2118

UKS INTERNATIONAL QUALITY SYSTEMS & CERTIFICATION LTD.

This is to certify

DENTA PHARMA

Dentaparma Ilac Medikal Gida San. Ve Tic. Ltd. Sti.

Kalaba Mh. Ahmet Vefik Pasa Cd. No: 13/B Kecioren / ANKARA TURKEY

Has been assessed by UKS and found to be in compliance with the following standard

ISO 9001:2015

The Quality Management System is applicable to

Personal Protective FFP Type Masks, Surgical / Medial Face Masks, Protective Coveralls, Doctor and Patient Gowns, Surgical Coverage, Surgical Cover Sets, Non- sterile Latex, Vinyl, Nitrile Nonpowdered and Powdered Examination Gloves, Sterile Powdered and Nonpowdered Surgical Gloves (latex, nitrile), Boots, Overshoe Covers and Surgial Bonnet Production

Category / Sub Category	: ---
Certificate No	:MSQ-0170
Certificate First Issue Date	:08th June 2020
Decision Date	:08th June 2020
Certificate Issue Date	:07th June 2021
Expiration Date	:07th June 2022

This certificate is valid for 3 years after first certification or re-certification decision date, in case of, firms to comply with UKS's Certification Rules and be successful in the surveillance audit made at least once a year.
FR.73/Issue Date:01.05.2013/Rev. Date:14.03.2019/Rev. No:04

CAS ACCREDITED CAS-MS-0011

Genel Müdür

UKS INTERNATIONAL QUALITY SYSTEMS & CERTIFICATION LTD.

UKS International Quality Systems & Certification Ltd.
Atakent Mah. Dicle Cad. No:35 Umraniye / ISTANBUL / TURKEY
Phone: +90 216 330 45 77 Pbx Faks: +90 216 330 67 47
info@uksbelgelendirme.com.tr

UKS INTERNATIONAL QUALITY SYSTEMS & CERTIFICATION LTD.

This is to certify

DENTA PHARMA

Dentaparma Ilac Medikal Gida San. Ve Tic. Ltd. Sti.

Kalaba Mh. Ahmet Vefik Pasa Cd. No: 13/B Kecioren / ANKARA

TURKEY

Has been assessed by UKS and found to be in compliance with the following standard

ISO 13485:2016

The Quality Medical Devices Management System is applicable to;

Personal Protective FFP Type Masks, Surgical / Medial Face Masks, Protective Coveralls, Doctor and Patient Gowns, Surgical Coverage, Surgical Cover Sets, Non- sterile Latex, Vinyl, Nitrile Nonpowdered and Powdered Examination Gloves, Sterile Powdered and Nonpowdered Surgical Gloves (latex, nitrile), Boots, Overshoe Covers and Surgial Bonnet Production

Category / Sub Category	: ---
Certificate No	:MDQ-0077
Certificate First Issue Date	:08th June 2020
Decision Date	:08th June 2020
Certificate Issue Date	:07th June 2021
Expiration Date	:07th June 2022

This certificate is valid for 3 years after first certification or re-certification decision date, in case of, firms to comply with UKS's Certification Rules and be successful in the surveillance audit made at least once a year.
FR.73/Issue Date:01.05.2013/Rev. Date:14.03.2019/Rev. No:04

CAS ACCREDITED CAS-MS-0011

Genel Müdür

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Atakent Mah. Dicle Cad. No:35 Umraniye/ISTANBUL/TURKEY
Phone: +90 216 330 45 77 Pbx Faks: +90 216 330 67 47
info@uksbelgelendirme.com.tr

TECHNICAL DATA SHEET

DGown DG06 Isolation Gown

It is made from a Non-woven SS fabric. It offers exceptional protection against fluids under minimal liquid pressure conditions.

KEY FEATURES

- These gowns are for single-use.
- Side ties eliminate difficulties of tying behind the back.
- They include functional cuffs constructed of a elastic material.
- Does not contain latex and phthalates.
- Water-repellent.
- Provided non-sterile.

APPROVALS

Fulfill the requirements for Class I MDD under Medical Device Regulation (EU) 2017/745. These gowns also fulfill all essential requirements and the related rules of the European Economic Commission 93/42/EEC Medical Devices Regulation (MDR). They also comply with AAMI Protective Barriers classification system and the associated minimum requirements for the liquid barrier performance of protective appparel and drapes based on ANSI standards.

NON-STERILE

SIZING

An appropriate size garment should be selected to allow sufficient movement for the task whilst maintaining a secure fit.

SIZE CHART

SIZE	HEIGHT	CHEST
S	116 cm	65 cm
M	118 cm	68 cm
L	120 cm	71 cm
XL	122 cm	74 cm
XXL	124 cm	77 cm
3XL	126 cm	80 cm

MATERIALS

SUIT	Non-woven SS
WEIGHT	30 gr/m2

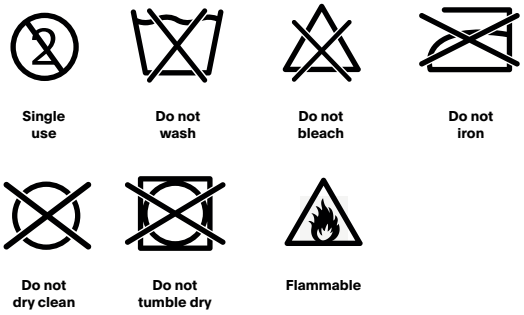
STORAGE AND DISPOSAL

- Store in dry, clean conditions in original packaging, away from direct sunlight, sources of high temperature, and solvent vapours.
- Expected shelf life is five years from the date of manufacture when stored as stated.
- Replace garment if damaged, heavily contaminated or in accordance with local work practice or regulations.
- Handle and dispose of contaminated garments with care and in accordance with applicable regulations.

WARNING AND LIMITATIONS

Make sure that product is suitable for the application and fitted correctly.Product must never be altered or modified. Final determination as to the suitability of these product for a particular situation is the employer's responsibility. This information is subject to revision at any time.

LIMITED USE



INTENDED USE

- Intended to protect from the transfer of microorganisms and bodily fluids in low risk patient isolation situations.
- Not intended for high risk surgical procedures, or where the risk of contamination is high.

PACKAGING

Each gown is individually folded and packaged into a bag

Kalaba Mah. Ahmet Vefik Paşa Cad. No:13/B Keçiören Ankara/TURKEY
Tel: (+90 312) 359 00 50 Fax: (+90 312) 359 00 53 Email: info@dentapharma.com whatsapp: +90 537 273 02 88
www.dentapharma.com

Denta Pharma İlaç Medikal San. ve Tic. Ltd. Şti.

DG06 I Single-use 30 gsm Medical Gown – *Camice medico 30 gr/mq non riutilizzabile*
DG06 Medical gown is designed to be used in low-risk low concentration contaminated areas to prevent particulate transfer hazards. It is manufactured in compliance with EN 13485 standarts.
These gowns also fulfil essential requirements and the related rules of REGULATION (EU) 2017/745.

Il camice medico DG06 è progettato per essere utilizzato in aree contaminate a bassa concentrazione a basso rischio per evitare i rischi di trasferimento di particolato. È prodotto in conformità alle norme EN 13485.
Questi camici soddisfano anche i requisiti essenziali e il Regolamento sui Dispositivi Medici(EU) 2017/745).

Intended use - *Destinazione d'uso*
For use in clinical and laboratory settings. Intended to protect from the transfer of microorganisms and bodily fluids in low or minimal risk patient isolation situations. Not intended *tor* high risk surgical procedures, or where the risk of contamination is high
Per l'uso in ambienti clinici e di laboratorio. Inteso a proteggere dal trasferimento di microrganismi e fluidi corporei in situazioni di isolamento del paziente a basso o minimo rischio. Non destinato a procedure chirurgiche ad alto rischio o dove il rischio di contaminazione è alto

Warning and limitations - *Avvertenze e limitazioni*
Make sure that the product is suitable for the application and fitted correctly. Product must never be altered or modified. Final determination as to the suitability of these products for a particular situation is the employer's responsibility. This information is subject to revision at any time. Latex free. If you have questions you may contact the manufacturer.
Verificare che il prodotto sia idoneo all'applicazione e indossato correttamente. Il prodotto non deve mai essere alterato o modificato. La determinazione finale dell'idoneità di questi prodotti in base alla sua destinazione d'uso è responsabilità del datore di lavoro. Queste informazioni sono soggette a revisione in qualsiasi momento. Latex free. In caso di domande, contattare il fabbricante

Storage and disposal - *Stoccaggio e smaltimento*
Store in dry, clean conditions in original packaging, away from direct sunlight, sources of high temperature, and solvent vapours. Expected shelf life is three years from the date of manufacture when stored as stated. Replace garment if damaged, heavily contaminated or in accordance with local work practice or regulations. Handle and dispose of contaminated garments with care in accordance with applicable local regulations.
Conservare in condizioni asciutte e pulite nella confezione originale, lontano dalla luce solare diretta, da fonti di alta temperatura e da vapori di solventi. La durata di conservazione prevista è di tre anni dalla data di produzione se conservata come indicato. Sostituire l'indumento se danneggiato, fortemente contaminato o in conformità con le pratiche o le normative di lavoro locali. Maneggiare e smaltire gli indumenti contaminati con cura in conformità con le normative locali applicabili

Manufactured by: - *Fabbricato da:*
Dentapharma İlaç Medikal San ve Tic Ltd. Şti.
Kalaba Mah. Ahmet Vefik Paşa Cad. No:13/b
Keçiören/ANKARA/TURKEY
+312 359 00 50
www.dentapharma.com
Made in Turkey

Single use only – Non riutilizzare	Non sterile		CE example – *Esempio di marcatura*
2	NON STERILE	CE	

Size - *Taglia*: XL
: 08/2021
: 08/2026
LOT: 210016

Noted: To avoid danger of suffocation, please keep this wrapper away from babies and children.
Nota: per evitare il pericolo di soffocamento, tenere questo sacchetto lontano da neonati e bambini.

DENTA PHARMA

Denta Pharma İlaç Medikal San. ve Tic. Ltd. Şti.

CAMICE - DG06

Tessuto TNT SS 30 g/m²

L

100% Polipropilene

Non riutilizzare

Regolamento (EU) 2017/745
Classe 1

MD

LOT

LOT N. MM/YY

MADE IN TURKEY

CE

Dentapharma İlaç Medikal San ve Tic Ltd. Şti. ,
Kalaba Mah. Ahmet Vefik Paşa Cad.
No:13/b Keçiören Ankara/TURKEY

Eko Goriva d.o.o. -
Ferrarska ulica, 2 6000 Koper (SI)

DENTA PHARMA

Denta Pharma İlaç Medikal San. ve Tic. Ltd. Şti.

Model No: Camice DGown DG06

Materiale: Tessuto TNT SS 30 g/m²

Taglia: L

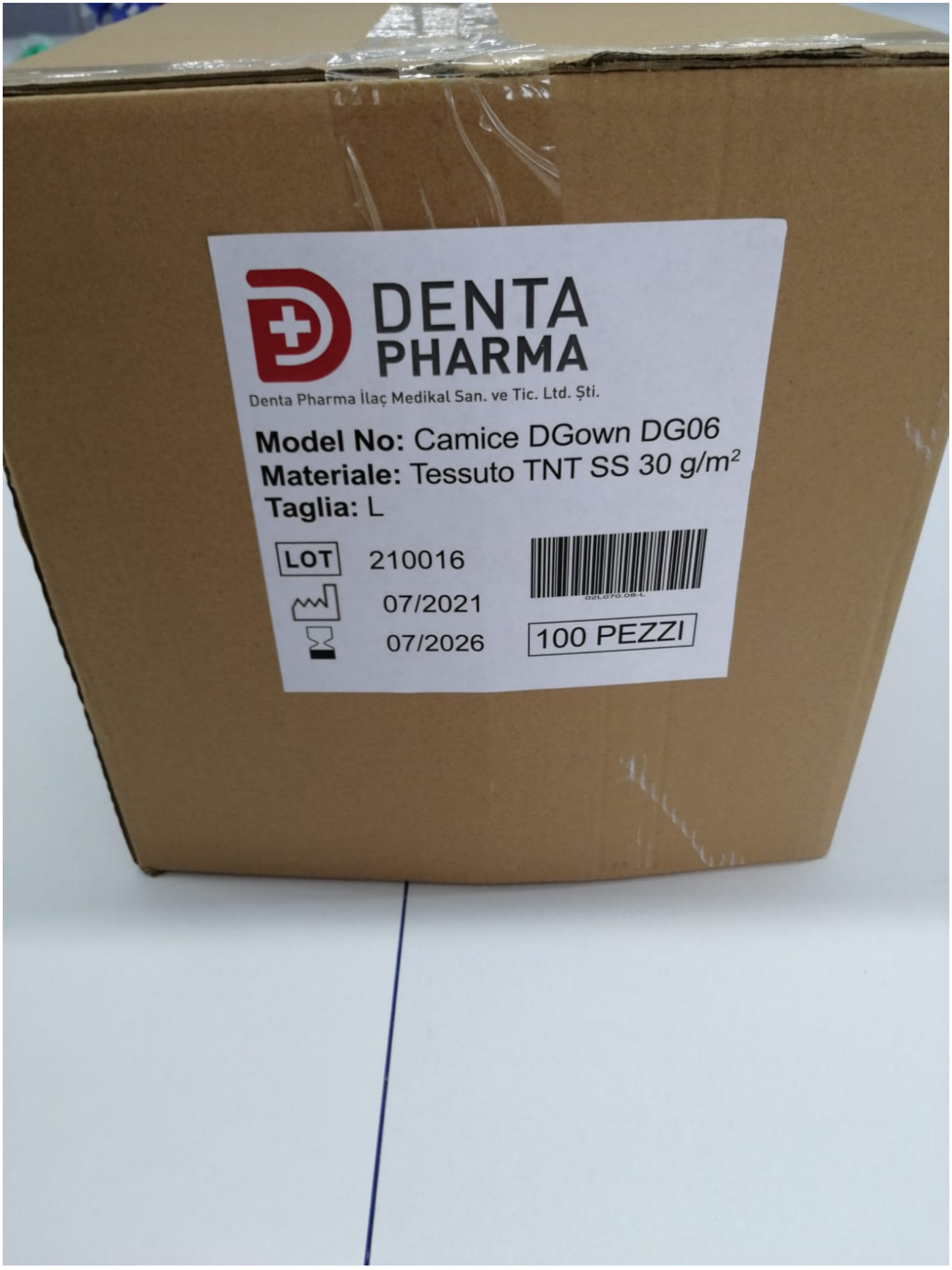
LOT 210016

07/2021

07/2026

02L070.08-L

100 PEZZI


DENTA
PHARMA
Denta Pharma İlaç Medikal San. ve Tic. Ltd. Şti.
Model No: Camice DGown DG06
Materiale: Tessuto TNT SS 30 g/m²
Taglia: L
LOT
210016
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07/2026
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