EC DECLARATION OF CONFORMITY

KLAS MEDİKAL CİHAZLAR SANAYİ MÜMESSİLLİK İÇ VE DIŞ TİC LTD.ŞTİ
FACTORY : RAMAZANOĞLU MAHALLESİ MAHSUS SOKAK KLAS MEDİKAL BLOK NO: 1 İÇ KAPI NO: 1 PENDİK 34906 İSTANBUL/TURKEY
Tel: +90 216 576 48 88 **Fax**: +90 216 577 82 97 **Email:** info@klasmedical.com

KLAS MEDİKAL CİH.SAN.MUM.İÇ VE DIŞ. TİC.LTD.ŞTİ.

Product : **SURGICAL INCISE DRAPE**
Classification : **Class Is Rule 1**
Brand : **HITEC**
GMDN Code : **47783**

Digitally signed by Cojocaru Vera
Date: 2023.09.17 12:29:04 EEST
Reason: MoldSign Signature
Location: Moldova

Applicable Directive and Standards:

Medical Devices Directive (MDD) 93/42/EEC + 2007/47/EC
Medical Device Regulation EU 2017/745(Article 120)+ *Regulation(EU)2023/607*

EN ISO 13485:2016+A11:2021	EN ISO 14937:2009	ASTM D3654-2019
EN ISO 11135:2014+A1:2019	EN ISO 14644-1:2015	EN ISO 14644-2:2015
EN ISO 14644-3:2019	EN ISO 20417:2021	EN ISO 15223-1:2021
EN ISO 14971:2019+A11:2021	EN ISO 10993-1:2020	EN ISO 10993-5:2009
EN ISO 10993-7:2008+A1:2022	EN ISO 10993-10:2021	EN ISO 11737-1:2018 +A1:2021
EN ISO 11737-2:2020	ASTM F 1980-2021	ASTM F 1929-2015
EN ISO 11607-1:2020+A11:2022	EN ISO 11607-2:2020+A11:2022	EN 17141:2020
EN ISO 22610:2006	EN ISO 22612:2005	TS 3957:2018
ISO/TR 20416:2020	EN ISO 20645:2004	*MDCG 2020-3 Rev.1*
MDCG 2020-7	MDCG 2020-8	MDCG 2019-7
MDCG 2021-1 Rev1	GHFT-SG2/N54R8:2006	

Method of Conformity Assessment: Annex 2 (excluding section 4)

REF(PE)	REF(PU)	SIZE(cm)	REF(PE)	REF(PU)	SIZE(cm)	REF(PE)	REF(PU)	SIZE(cm)	REF(PE)	REF(PU)	SIZE(cm)
D1010	DU1010	10x10	D3030	DU3030	30x30	D4540	DU4540	45x40	D6045	DU6045	60x45
D1012	DU1012	10x12	D3035	DU3035	30x35	D4545	DU4545	45x45	D6050	DU6050	60x50
D1020	DU1020	10x20	D3040	DU3040	30x40	D4548	DU4548	45x48	D6055	DU6055	60x55
D1030	DU1030	10x30	D3045	DU3045	30x45	D4555	DU4555	45x55	D6060	DU6060	60x60
D1050	DU1050	10x50	D3050	DU3050	30x50	D4560	DU4560	45x60	D6070	DU6070	60x70
D1060	DU1060	10x60	D3060	DU3060	30x60	D4565	DU4565	45x65	D6080	DU6080	60x80
D1520	DU1520	15x20	D3535	DU3535	35x35	D4590	DU4590	45x90	D6085	DU6085	60x85
D1528	DU1528	15x28	D3540	DU3540	35x40	D5045	DU5045	50x45	D6090	DU6090	60x90
D1530	DU1530	15x30	D3545	DU3545	35x45	D5060	DU5060	50x60	D6640	DU6640	66x40
D1620	DU1620	16x20	D3550	DU3550	35x50	D5545	DU5545	55x45	D6645	DU6645	66x45
D2010	DU2010	20x10	D3560	DU3560	35x60	D5580	DU5580	55x80	D6650	DU6650	66x50
D2020	DU2020	20x20	D4030	DU4030	40x30	D5640	DU5640	56x40	D6660	DU6660	66x60
D2030	DU2030	20x30	D4035	DU4035	40x35	D5645	DU5645	56x45	D6685	DU6685	66x85
D2040	DU2040	20x40	D4040	DU4040	40x40	D5660	DU5660	56x60	D6690	DU6690	66x90
D2815	DU2815	28x15	D4042	DU4042	40x42	D5680	DU5680	56x80	D9045	DU9045	90x45
D2830	DU2830	28x30	D4045	DU4045	40x45	D5685	DU5685	56x85	D9050	DU9050	90x50
D2840	DU2840	28x40	D4060	DU4060	40x60	D5690	DU5690	56x90	D9060	DU9060	90x60
D2845	DU2845	28x45	D4528	DU4528	45x28	D6030	DU6030	60x30			
D3020	DU30x20	30x20	D4530	DU4530	45x30	D6035	DU6035	60x35			
D3027	DU3027	30x27	D4535	DU4535	45x35	D6040	DU6040	60x40			

We declare that the products mentioned in model table meet the relevant provisions of the Council Directive 93/42/EEC and 2007/47/EC for Medical Devices and the products are manufactured according to certified quality assurance system provisions.

SIGNATURES

Prepared by : **Hatice ÖZTÜRK**
Position : **Quality Assurance Manager**

Approved by : **Selvi ÖZTÜRK**
Position : **Company Owner**

Place: Istanbul
Date: 29.05.2023

Notified Body : UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San.ve Tic. A.Ş.
Mutlukent Mahallesi 2073 Sokak No:10 Ümitköy-ÇANKAYA Ankara TURKEY
Notified Body No : 2292
Certificate No : M.2018.106.9577
Certificate Issue Date : 24.04.2018
Certificate Expiry Date : 23.04.2023

Extension Period within Scope of EU 2023/607 : *26.05.2024*

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2018.106.9577-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Klas Medikal Cihazlar Sanayi Mümessillik İç ve Dış Ticaret Limited Şirketi
Company Address	: Ramazanoğlu Mahallesi Mahsus Sokak Klas Medikal Blok No: 1 İç Kapı No:1 Pendik İSTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Neurosurgical Sponge - Class III, Sterile Mesh and Kits for Incontinence - Class IIb, Sterile Mesh for Hernia - Class IIb, Sterile Surgical Incise Drape - Class Is, Sterile
GMDN	: 13702, 47986, 60842, 61337, 60300, 47783

Product Types are attached.

Certificate Number	: M.2018.106.9577
Report Number	: MD.3466.IB
Initial Assessment Date	: 15.12.2017
Registration Date	: 24.04.2018
Revision Date /No	: 06.05.2021/04
Expiry Date	: 23.04.2023

UDEM APPROVED 2292

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive 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 II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. 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 device 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 returnedupon 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 thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

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

UDEM

MDD EXTENSION APPROVAL LETTER

02/05/2023

To whom It May Concern,

As UDEM A.Ş., operating as a notified body within the scope of the 93/42/EEC Medical Device Directive, we have issued an EC certificate on 24.04.2018 for the companies and products whose information is given in Table-1, within the scope of the 93/42/EEC Medical Device Regulations. We declare that the certificate is valid for the products specified in Table-1 until the expiry date.

Table-1

Company Name	EC Certificate No	Scope	Expiry Date
KLAS MEDİKAL CİHAZLAR SANAYİ MÜMESSİLLİK İÇ VE DIŞ TİC. LTD.ŞTİ.	M.2018.106.9577	- STERILE NEUROSURGICAL SPONGE - STERILE MESH FOR INCONTINENCE - STERILE MESH FOR HERNIA -SURGICAL INCISE DRAPE	23.04.2023

UDFRM.305 Extension Process Information Form On EC Certificates Applicable Under 9342EEC has been provided from the relevant company in order to confirm the applicability of the provisions regarding the extension of the validity periods of the 93/42/EEC certificates within the scope of the Regulation on the Amendment of the Medical Device Regulation published in the Official Gazette dated April 2, 2023 and numbered 32151. When the information provided by the company is reviewed, it has been shared that no application has been made to another notified body authorized under (EU) 2017/745 for the products covered by the EC certificate.

In accordance with the Regulation on the Amendment of the Medical Device Regulation, for the above-mentioned company for its products within the scope of the EC certificate given in Table-1, Art. We hereby declare that we have assumed the responsibility of surveillance as specified in subparagraph 120 (3e) until 26 May 2024 with UDFRM.07-2 Additional Contract On Extension Of The Validity Period Of EC Certificates signed by the relevant company and UDEM A.Ş. on 02/05/2023

The execution of the said surveillance audits will continue depending on the company's fulfillment of the obligations set forth in Article 120 (3c) of the relevant Regulation.

Serian DOMA
Medical Device Technical Regulation Responsbile

UDEM ULUSLARARASI BELGELENDİRME
UDEM DEN. EĞT. MERK. SAN. VE TİC. A.Ş.
Mutlukent Mah. 2073. Sk. No:10 Ümitköy - Çankaya / ANKARA
Tel: (0.312) 443 03 90 (pbx) Fax: (0.312) 443 03 76
DOĞANBEY Vergi Dairesi : 885 044 2567

T:+90 312 443 03 90 F: +90 312 443 03 76 E-mail: info@udem.com.tr
Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya / ANKARA

This document containing 5 (five) pages is the Annex of the Certificate with the revision number 04, with the number M.2018.106.9577 and with the registration date of 24.04.2018 and with the revision date of 06.05.2021 issued for "Klas Medikal Cihazlar Sanayi Mümessillik İç ve Dış Ticaret Limited Şirketi" by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Neurosurgical Sponge

Ref. No	Description	GMDN	Ref. No	Description	GMDN
HSSK0505	HITEC Neurosurgical Sponge 5x5 mm	13702	HSSK1350	HITEC Neurosurgical Sponge 13x50 mm	13702
HSSK0510	HITEC Neurosurgical Sponge 5x10 mm	13702	HSSK1376	HITEC Neurosurgical Sponge 13x76 mm	13702
HSSK0707	HITEC Neurosurgical Sponge 7x7 mm	13702	HSSK1520	HITEC Neurosurgical Sponge 15x20 mm	13702
HSSK0738	HITEC Neurosurgical Sponge 7x38 mm	13702	HSSK1530	HITEC Neurosurgical Sponge 15x30 mm	13702
HSSK0776	HITEC Neurosurgical Sponge 7x76 mm	13702	HSSK2010	HITEC Neurosurgical Sponge 20x10 mm	13702
HSSK1010	HITEC Neurosurgical Sponge 10x10 mm	13702	HSSK2020	HITEC Neurosurgical Sponge 20x20 mm	13702
HSSK1015	HITEC Neurosurgical Sponge 10x15 mm	13702	HSSK2025	HITEC Neurosurgical Sponge 20x25 mm	13702
HSSK1020	HITEC Neurosurgical Sponge 10x20 mm	13702	HSSK2030	HITEC Neurosurgical Sponge 20x30 mm	13702
HSSK1030	HITEC Neurosurgical Sponge 10x30 mm	13702	HSSK2040	HITEC Neurosurgical Sponge 20x40 mm	13702
HSSK1040	HITEC Neurosurgical Sponge 10x40 mm	13702	HSSK2050	HITEC Neurosurgical Sponge 20x50 mm	13702
HSSK1050	HITEC Neurosurgical Sponge 10x50 mm	13702	HSSK2060	HITEC Neurosurgical Sponge 20x60 mm	13702
HSSK1060	HITEC Neurosurgical Sponge 10x60 mm	13702	HSSK2070	HITEC Neurosurgical Sponge 20x70 mm	13702
HSSK1070	HITEC Neurosurgical Sponge 10x70 mm	13702	HSSK2075	HITEC Neurosurgical Sponge 20x75 mm	13702
HSSK1075	HITEC Neurosurgical Sponge 10x75 mm	13702	HSSK25125	HITEC Neurosurgical Sponge 25x12,5 mm	13702
HSSK1212	HITEC Neurosurgical Sponge 12x12 mm	13702	HSSK2525	HITEC Neurosurgical Sponge 25x25 mm	13702
HSSK1225	HITEC Neurosurgical Sponge 12x25 mm	13702	HSSK2530	HITEC Neurosurgical Sponge 25x30 mm	13702
HSSK1230	HITEC Neurosurgical Sponge 12x30 mm	13702	HSSK2540	HITEC Neurosurgical Sponge 25x40 mm	13702
HSSK1240	HITEC Neurosurgical Sponge 12x40 mm	13702	HSSK2550	HITEC Neurosurgical Sponge 25x50 mm	13702
HSSK1250	HITEC Neurosurgical Sponge 12x50 mm	13702	HSSK2560	HITEC Neurosurgical Sponge 25x60 mm	13702
HSSK1260	HITEC Neurosurgical Sponge 12x60 mm	13702	HSSK2575	HITEC Neurosurgical Sponge 25x75 mm	13702
HSSK1270	HITEC Neurosurgical Sponge 12x70 mm	13702	HSSK2576	HITEC Neurosurgical Sponge 25x76 mm	13702
HSSK1275	HITEC Neurosurgical Sponge 12x75 mm	13702	HSSK30125	HITEC Neurosurgical Sponge 30x12,5 mm	13702
HSSK125125	HITEC Neurosurgical Sponge 12,5x12,5 mm	13702	HSSK3030	HITEC Neurosurgical Sponge 30x30 mm	13702
HSSK12520	HITEC Neurosurgical Sponge 12,5x20 mm	13702	HSSK3050	HITEC Neurosurgical Sponge 30x50 mm	13702
HSSK12525	HITEC Neurosurgical Sponge 12,5x25 mm	13702	HSSK3530	HITEC Neurosurgical Sponge 35x30 mm	13702
HSSK12530	HITEC Neurosurgical Sponge 12,5x30 mm	13702	HSSK3838	HITEC Neurosurgical Sponge 38x38 mm	13702
HSSK12540	HITEC Neurosurgical Sponge 12,5x40 mm	13702	HSSK4010	HITEC Neurosurgical Sponge 40x10 mm	13702
HSSK12550	HITEC Neurosurgical Sponge 12,5x50 mm	13702	HSSK4020	HITEC Neurosurgical Sponge 40x20 mm	13702
HSSK12570	HITEC Neurosurgical Sponge 12,5x70 mm	13702	HSSK4040	HITEC Neurosurgical Sponge 40x40 mm	13702
HSSK12575	HITEC Neurosurgical Sponge 12,5x75 mm	13702	HSSK4050	HITEC Neurosurgical Sponge 40x50 mm	13702
HSSK127127	HITEC Neurosurgical Sponge 12,7x12,7 mm	13702	HSSK4070	HITEC Neurosurgical Sponge 40x70 mm	13702
HSSK1313	HITEC Neurosurgical Sponge 13x13 mm	13702	HSSK4075	HITEC Neurosurgical Sponge 40x75 mm	13702
HSSK1320	HITEC Neurosurgical Sponge 13x20 mm	13702	HSSK5050	HITEC Neurosurgical Sponge 50x50 mm	13702
HSSK1325	HITEC Neurosurgical Sponge 13x25 mm	13702	HSSK5070	HITEC Neurosurgical Sponge 50x70 mm	13702
HSSK1338	HITEC Neurosurgical Sponge 13x38 mm	13702			

Ref. No	Description	GMDN	Ref. No	Description	GMDN
SS0505	SUPRO Neurosurgical Sponge 5x5 mm	13702	SS1350	SUPRO Neurosurgical Sponge 13x50 mm	13702
SS0510	SUPRO Neurosurgical Sponge 5x10 mm	13702	SS1376	SUPRO Neurosurgical Sponge 13x76 mm	13702
SS0707	SUPRO Neurosurgical Sponge 7x7 mm	13702	SS1520	SUPRO Neurosurgical Sponge 15x20 mm	13702
SS0738	SUPRO Neurosurgical Sponge 7x38 mm	13702	SS1530	SUPRO Neurosurgical Sponge 15x30 mm	13702
SS0776	SUPRO Neurosurgical Sponge 7x76 mm	13702	SS2010	SUPRO Neurosurgical Sponge 20x10 mm	13702
SS1010	SUPRO Neurosurgical Sponge 10x10 mm	13702	SS2020	SUPRO Neurosurgical Sponge 20x20 mm	13702
SS1015	SUPRO Neurosurgical Sponge 10x15 mm	13702	SS2025	SUPRO Neurosurgical Sponge 20x25 mm	13702
SS1020	SUPRO Neurosurgical Sponge 10x20 mm	13702	SS2030	SUPRO Neurosurgical Sponge 20x30 mm	13702
SS1030	SUPRO Neurosurgical Sponge 10x30 mm	13702	SS2040	SUPRO Neurosurgical Sponge 20x40 mm	13702
SS1040	SUPRO Neurosurgical Sponge 10x40 mm	13702	SS2050	SUPRO Neurosurgical Sponge 20x50 mm	13702
SS1050	SUPRO Neurosurgical Sponge 10x50 mm	13702	SS2060	SUPRO Neurosurgical Sponge 20x60 mm	13702
SS1060	SUPRO Neurosurgical Sponge 10x60 mm	13702	SS2070	SUPRO Neurosurgical Sponge 20x70 mm	13702
SS1070	SUPRO Neurosurgical Sponge 10x70 mm	13702	SS2075	SUPRO Neurosurgical Sponge 20x75 mm	13702
SS1075	SUPRO Neurosurgical Sponge 10x75 mm	13702	SS25125	SUPRO Neurosurgical Sponge 25x12,5 mm	13702
SS1212	SUPRO Neurosurgical Sponge 12x12 mm	13702	SS2525	SUPRO Neurosurgical Sponge 25x25 mm	13702
SS1225	SUPRO Neurosurgical Sponge 12x25 mm	13702	SS2530	SUPRO Neurosurgical Sponge 25x30 mm	13702
SS1230	SUPRO Neurosurgical Sponge 12x30 mm	13702	SS2540	SUPRO Neurosurgical Sponge 25x40 mm	13702
SS1240	SUPRO Neurosurgical Sponge 12x40 mm	13702	SS2550	SUPRO Neurosurgical Sponge 25x50 mm	13702
SS1250	SUPRO Neurosurgical Sponge 12x50 mm	13702	SS2560	SUPRO Neurosurgical Sponge 25x60 mm	13702
SS1260	SUPRO Neurosurgical Sponge 12x60 mm	13702	SS2575	SUPRO Neurosurgical Sponge 25x75 mm	13702

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SS1270	SUPRO Neurosurgical Sponge 12x70 mm	13702	SS2576	SUPRO Neurosurgical Sponge 25x76 mm	13702
SS1275	SUPRO Neurosurgical Sponge 12x75 mm	13702	SS30125	SUPRO Neurosurgical Sponge 30x12,5 mm	13702
SS125125	SUPRO Neurosurgical Sponge 12,5x12,5 mm	13702	SS3030	SUPRO Neurosurgical Sponge 30x30 mm	13702
SS12520	SUPRO Neurosurgical Sponge 12,5x20 mm	13702	SS3050	SUPRO Neurosurgical Sponge 30x50 mm	13702
SS12525	SUPRO Neurosurgical Sponge 12,5x25 mm	13702	SS3530	SUPRO Neurosurgical Sponge 35x30 mm	13702
SS12530	SUPRO Neurosurgical Sponge 12,5x30 mm	13702	SS3838	SUPRO Neurosurgical Sponge 38x38 mm	13702
SS12540	SUPRO Neurosurgical Sponge 12,5x40 mm	13702	SS4010	SUPRO Neurosurgical Sponge 40x10 mm	13702
SS12550	SUPRO Neurosurgical Sponge 12,5x50 mm	13702	SS4020	SUPRO Neurosurgical Sponge 40x20 mm	13702
SS12570	SUPRO Neurosurgical Sponge 12,5x70 mm	13702	SS4040	SUPRO Neurosurgical Sponge 40x40 mm	13702
SS12575	SUPRO Neurosurgical Sponge 12,5x75 mm	13702	SS4050	SUPRO Neurosurgical Sponge 40x50 mm	13702
SS127127	SUPRO Neurosurgical Sponge 12,7x12,7 mm	13702	SS4070	SUPRO Neurosurgical Sponge 40x70 mm	13702
SS1313	SUPRO Neurosurgical Sponge 13x13 mm	13702	SS4075	SUPRO Neurosurgical Sponge 40x75 mm	13702
SS1320	SUPRO Neurosurgical Sponge 13x20 mm	13702	SS5050	SUPRO Neurosurgical Sponge 50x50 mm	13702
SS1325	SUPRO Neurosurgical Sponge 13x25 mm	13702	SS5070	SUPRO Neurosurgical Sponge 50x70 mm	13702
SS1338	SUPRO Neurosurgical Sponge 13x38 mm	13702			

Mesh and Kits for Incontinence

Ref. No	Description	GMDN	Ref. No	Description	GMDN
VT1045	SUPRO Vaginal Tape 10x450mm	47986	KIT CYS-2	SUPRO Cystocele Kit 60x80x380mm	60842
VT1050	SUPRO Vaginal Tape 10x500mm	47986	KIT MINI	SUPRO Mini Kit 12x80mm	47986
VT1060	SUPRO Vaginal Tape 10x600mm	47986	SP-01	SUPRO Suprapubic Needle	61337
VT1280	SUPRO Vaginal Tape 12X80mm	47986	TO-01	SUPRO Transobturator Needle	61337
VT1245	SUPRO Vaginal Tape 12x450mm	47986	HA-02	SUPRO Helical Needle	61337
CYS	SUPRO Cystocele Tape 60x80x380mm	60842	VTUSS1045	HITEC Vaginal Tape 10x450mm	47986
CYS-2	SUPRO Cystocele Tape 60x80x380mm	60842	VTUSS1050	HITEC Vaginal Tape 10x500mm	47986
REC	SUPRO Rectocele Tape 40x100x300mm	60842	VTUSS1060	HITEC Vaginal Tape 10x600mm	47986
KIT TO-01	SUPRO Transobturator Kit 10x450mm	47986	VTUSS1280	HITEC Vaginal Tape 12X80mm	47986
KIT SP-01	SUPRO Suprapubic Kit 10x600mm	47986	VTUSS1245	HITEC Vaginal Tape 12x450mm	47986
KIT SP-015	SUPRO Suprapubic Kit 10x500mm	47986	TOTUSS	HITEC Transobturator Kit 10x450mm	47986
KIT HA-02	SUPRO Helical Kit 10x450mm	47986	PUBICUSS	HITEC Suprapubic Kit 10x600mm	47986
KIT REC	SUPRO Rectocele Kit 40x100x300mm	60842	HELUSS	HITEC Helical Kit 10x450mm	47986
KIT CYS	SUPRO Cystocele Kit 60x80x380mm	60842			

Mesh for Hernia

Ref. No	Description	GMDN	Ref. No	Description	GMDN
SMS0406	SUPRO Mesh for Hernia Light 4x6 cm	60300	SMS1030	SUPRO Mesh for Hernia Light 10x30 cm	60300
SMS0505	SUPRO Mesh for Hernia Light 5x5 cm	60300	SMS1510	SUPRO Mesh for Hernia Light 15x10 cm	60300
SMS0508	SUPRO Mesh for Hernia Light 5x8 cm	60300	SMS1515	SUPRO Mesh for Hernia Light 15x15 cm	60300
SMS0510	SUPRO Mesh for Hernia Light 5x10 cm	60300	SMS1520	SUPRO Mesh for Hernia Light 15x20 cm	60300
SMS0611	SUPRO Mesh for Hernia Light 6x11 cm	60300	SMS1530	SUPRO Mesh for Hernia Light 15x30 cm	60300
SMS0614	SUPRO Mesh for Hernia Light 6x14 cm	60300	SMS2020	SUPRO Mesh for Hernia Light 20x20 cm	60300
SMS0712	SUPRO Mesh for Hernia Light 7x12 cm	60300	SMS2030	SUPRO Mesh for Hernia Light 20x30 cm	60300
SMS7575	SUPRO Mesh for Hernia Light 7,5x7,5 cm	60300	SMS2235	SUPRO Mesh for Hernia Light 22x35 cm	60300
SMS7515	SUPRO Mesh for Hernia Light 7,5x15 cm	60300	SMS2510	SUPRO Mesh for Hernia Light 25x10 cm	60300
SMS0813	SUPRO Mesh for Hernia Light 8x13 cm	60300	SMS3015	SUPRO Mesh for Hernia Light 30x15 cm	60300
SMS0814	SUPRO Mesh for Hernia Light 8x14 cm	60300	SMS3030	SUPRO Mesh for Hernia Light 30x30 cm	60300
SMS0815	SUPRO Mesh for Hernia Light 8x15 cm	60300	SMS3040	SUPRO Mesh for Hernia Light 30x40 cm	60300
SMS1010	SUPRO Mesh for Hernia Light 10x10 cm	60300	SMS3050	SUPRO Mesh for Hernia Light 30x50 cm	60300
SMS1013	SUPRO Mesh for Hernia Light 10x13 cm	60300	SMS4040	SUPRO Mesh for Hernia Light 40x40 cm	60300
SMS1015	SUPRO Mesh for Hernia Light 10x15 cm	60300	SMS6060	SUPRO Mesh for Hernia Light 60x60 cm	60300

Ref. No	Description	GMDN	Ref. No	Description	GMDN
SMM0406	SUPRO Mesh for Hernia 4x6 cm	60300	SMM1030	SUPRO Mesh for Hernia 10x30 cm	60300
SMM0505	SUPRO Mesh for Hernia 5x5 cm	60300	SMM1510	SUPRO Mesh for Hernia 15x10 cm	60300
SMM0508	SUPRO Mesh for Hernia 5x8 cm	60300	SMM1515	SUPRO Mesh for Hernia 15x15 cm	60300
SMM0510	SUPRO Mesh for Hernia 5x10 cm	60300	SMM1520	SUPRO Mesh for Hernia 15x20 cm	60300

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

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SMM0611	SUPRO Mesh for Hernia 6x11 cm	60300	SMM1530	SUPRO Mesh for Hernia 15x30 cm	60300
SMM0614	SUPRO Mesh for Hernia 6x14 cm	60300	SMM2020	SUPRO Mesh for Hernia 20x20 cm	60300
SMM0712	SUPRO Mesh for Hernia 7x12 cm	60300	SMM2030	SUPRO Mesh for Hernia 20x30 cm	60300
SMM7575	SUPRO Mesh for Hernia 7,5x7,5 cm	60300	SMM2235	SUPRO Mesh for Hernia 22x35 cm	60300
SMM7515	SUPRO Mesh for Hernia 7,5x15 cm	60300	SMM2510	SUPRO Mesh for Hernia 25x10 cm	60300
SMM0813	SUPRO Mesh for Hernia 8x13 cm	60300	SMM3015	SUPRO Mesh for Hernia 30x15 cm	60300
SMM0814	SUPRO Mesh for Hernia 8x14 cm	60300	SMM3030	SUPRO Mesh for Hernia 30x30 cm	60300
SMM0815	SUPRO Mesh for Hernia 8x15 cm	60300	SMM3040	SUPRO Mesh for Hernia 30x40 cm	60300
SMM1010	SUPRO Mesh for Hernia 10x10 cm	60300	SMM3050	SUPRO Mesh for Hernia 30x50 cm	60300
SMM1013	SUPRO Mesh for Hernia 10x13 cm	60300	SMM4040	SUPRO Mesh for Hernia 40x40 cm	60300
SMM1015	SUPRO Mesh for Hernia 10x15 cm	60300	SMM6060	SUPRO Mesh for Hernia 60x60 cm	60300

Ref. No	Description	GMDN	Ref. No	Description	GMDN
SML0406	SUPRO Mesh for Hernia Light 4x6 cm	60300	SML1030	SUPRO Mesh for Hernia Light 10x30 cm	60300
SML0505	SUPRO Mesh for Hernia Light 5x5 cm	60300	SML1510	SUPRO Mesh for Hernia Light 15x10 cm	60300
SML0508	SUPRO Mesh for Hernia Light 5x8 cm	60300	SML1515	SUPRO Mesh for Hernia Light 15x15 cm	60300
SML0510	SUPRO Mesh for Hernia Light 5x10 cm	60300	SML1520	SUPRO Mesh for Hernia Light 15x20 cm	60300
SML0611	SUPRO Mesh for Hernia Light 6x11 cm	60300	SML1530	SUPRO Mesh for Hernia Light 15x30 cm	60300
SML0614	SUPRO Mesh for Hernia Light 6x14 cm	60300	SML2020	SUPRO Mesh for Hernia Light 20x20 cm	60300
SML0712	SUPRO Mesh for Hernia Light 7x12 cm	60300	SML2030	SUPRO Mesh for Hernia Light 20x30 cm	60300
SML7575	SUPRO Mesh for Hernia Light 7,5x7,5 cm	60300	SML2235	SUPRO Mesh for Hernia Light 22x35 cm	60300
SML7515	SUPRO Mesh for Hernia Light 7,5x15 cm	60300	SML2510	SUPRO Mesh for Hernia Light 25x10 cm	60300
SML0813	SUPRO Mesh for Hernia Light 8x13 cm	60300	SML3015	SUPRO Mesh for Hernia Light 30x15 cm	60300
SML0814	SUPRO Mesh for Hernia Light 8x14 cm	60300	SML3030	SUPRO Mesh for Hernia Light 30x30 cm	60300
SML0815	SUPRO Mesh for Hernia Light 8x15 cm	60300	SML3040	SUPRO Mesh for Hernia Light 30x40 cm	60300
SML1010	SUPRO Mesh for Hernia Light 10x10 cm	60300	SML3050	SUPRO Mesh for Hernia Light 30x50 cm	60300
SML1013	SUPRO Mesh for Hernia Light 10x13 cm	60300	SML4040	SUPRO Mesh for Hernia Light 40x40 cm	60300
SML1015	SUPRO Mesh for Hernia Light 10x15 cm	60300	SML6060	SUPRO Mesh for Hernia Light 60x60 cm	60300

Ref. No	Description	GMDN	Ref. No	Description	GMDN
P3DS	SUPRO Mesh for Hernia Plug 3D Kit Ø3.4 cm	60300	P3DMS	SUPRO Mesh for Hernia Plug 3D Ø3.4 cm	60300
P3DM	SUPRO Mesh for Hernia Plug 3D Kit Ø4.5 cm	60300	P3DMM	SUPRO Mesh for Hernia Plug 3D Ø4.5 cm	60300
P3DL	SUPRO Mesh for Hernia Plug 3D Kit Ø5 cm	60300	P3DML	SUPRO Mesh for Hernia Plug 3D Ø5 cm	60300
PLG7	SUPRO Mesh for Hernia Plug Kit Ø7 cm	60300	SMK0509	SUPRO Mesh for Hernia Preshaped 5x9 cm	60300
PLG9	SUPRO Mesh for Hernia Plug Kit Ø9 cm	60300	SMK0611	SUPRO Mesh for Hernia Preshaped 6x11 cm	60300
PLG11	SUPRO Mesh for Hernia Plug Kit Ø11 cm	60300	SMK0614	SUPRO Mesh for Hernia Preshaped 6x14 cm	60300

Surgical Incise Drape

Ref. No	Description	GMDN	Ref. No	Description	GMDN
D1010	HITEC Surgical Incise Drape 10x10 cm	47783	D4535	HITEC Surgical Incise Drape 45x35 cm	47783
D1012	HITEC Surgical Incise Drape 10x12 cm	47783	D4540	HITEC Surgical Incise Drape 45x40 cm	47783
D1020	HITEC Surgical Incise Drape 10x20 cm	47783	D4545	HITEC Surgical Incise Drape 45x45 cm	47783
D1030	HITEC Surgical Incise Drape 10x30 cm	47783	D4548	HITEC Surgical Incise Drape 45x48 cm	47783
D1050	HITEC Surgical Incise Drape 10x50 cm	47783	D4555	HITEC Surgical Incise Drape 45x55 cm	47783
D1060	HITEC Surgical Incise Drape 10x60 cm	47783	D4560	HITEC Surgical Incise Drape 45x60 cm	47783
D1520	HITEC Surgical Incise Drape 15x20 cm	47783	D4565	HITEC Surgical Incise Drape 45x65 cm	47783
D1528	HITEC Surgical Incise Drape 15x28 cm	47783	D4590	HITEC Surgical Incise Drape 45x90 cm	47783
D1530	HITEC Surgical Incise Drape 15x30 cm	47783	D5045	HITEC Surgical Incise Drape 50x45 cm	47783
D1620	HITEC Surgical Incise Drape 16x20 cm	47783	D5060	HITEC Surgical Incise Drape 50x60 cm	47783
D2010	HITEC Surgical Incise Drape 20x10 cm	47783	D5545	HITEC Surgical Incise Drape 55x45 cm	47783
D2020	HITEC Surgical Incise Drape 20x20 cm	47783	D5580	HITEC Surgical Incise Drape 55x80 cm	47783
D2030	HITEC Surgical Incise Drape 20x30 cm	47783	D5640	HITEC Surgical Incise Drape 56x40 cm	47783
D2040	HITEC Surgical Incise Drape 20x40 cm	47783	D5645	HITEC Surgical Incise Drape 56x45 cm	47783
D2815	HITEC Surgical Incise Drape 28x15 cm	47783	D5660	HITEC Surgical Incise Drape 56x60 cm	47783

UDEM International Certification Auditing Training Service Industry and Trade Inc. Co.

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D2830	HITEC Surgical Incise Drape 28x30 cm	47783	D5680	HITEC Surgical Incise Drape 56x80 cm	47783
D2840	HITEC Surgical Incise Drape 28x40 cm	47783	D5685	HITEC Surgical Incise Drape 56x85 cm	47783
D2845	HITEC Surgical Incise Drape 28x45 cm	47783	D5690	HITEC Surgical Incise Drape 56x90 cm	47783
D3020	HITEC Surgical Incise Drape 30x20 cm	47783	D6030	HITEC Surgical Incise Drape 60x30 cm	47783
D3027	HITEC Surgical Incise Drape 30x27 cm	47783	D6035	HITEC Surgical Incise Drape 60x35 cm	47783
D3030	HITEC Surgical Incise Drape 30x30 cm	47783	D6040	HITEC Surgical Incise Drape 60x40 cm	47783
D3035	HITEC Surgical Incise Drape 30x35 cm	47783	D6045	HITEC Surgical Incise Drape 60x45 cm	47783
D3040	HITEC Surgical Incise Drape 30x40 cm	47783	D6050	HITEC Surgical Incise Drape 60x50 cm	47783
D3045	HITEC Surgical Incise Drape 30x45 cm	47783	D6055	HITEC Surgical Incise Drape 60x55 cm	47783
D3050	HITEC Surgical Incise Drape 30x50 cm	47783	D6060	HITEC Surgical Incise Drape 60x60 cm	47783
D3060	HITEC Surgical Incise Drape 30x60 cm	47783	D6070	HITEC Surgical Incise Drape 60x70 cm	47783
D3535	HITEC Surgical Incise Drape 35x35 cm	47783	D6080	HITEC Surgical Incise Drape 60x80 cm	47783
D3540	HITEC Surgical Incise Drape 35x40 cm	47783	D6085	HITEC Surgical Incise Drape 60x85 cm	47783
D3545	HITEC Surgical Incise Drape 35x45 cm	47783	D6090	HITEC Surgical Incise Drape 60x90 cm	47783
D3550	HITEC Surgical Incise Drape 35x50 cm	47783	D6640	HITEC Surgical Incise Drape 66x40 cm	47783
D3560	HITEC Surgical Incise Drape 35x60 cm	47783	D6645	HITEC Surgical Incise Drape 66x45 cm	47783
D4030	HITEC Surgical Incise Drape 40x30 cm	47783	D6650	HITEC Surgical Incise Drape 66x50 cm	47783
D4035	HITEC Surgical Incise Drape 40x35 cm	47783	D6660	HITEC Surgical Incise Drape 66x60 cm	47783
D4040	HITEC Surgical Incise Drape 40x40 cm	47783	D6685	HITEC Surgical Incise Drape 66x85 cm	47783
D4042	HITEC Surgical Incise Drape 40x42 cm	47783	D6690	HITEC Surgical Incise Drape 66x90 cm	47783
D4045	HITEC Surgical Incise Drape 40x45 cm	47783	D9045	HITEC Surgical Incise Drape 90x45 cm	47783
D4060	HITEC Surgical Incise Drape 40x60 cm	47783	D9050	HITEC Surgical Incise Drape 90x50 cm	47783
D4528	HITEC Surgical Incise Drape 45x28 cm	47783	D9060	HITEC Surgical Incise Drape 90x60 cm	47783
D4530	HITEC Surgical Incise Drape 45x30 cm	47783			

Ref. No	Description	GMDN	Ref. No	Description	GMDN
DU1010	HITEC Surgical Incise Drape PU 10x10 cm	47783	DU4535	HITEC Surgical Incise Drape PU 45x35 cm	47783
DU1012	HITEC Surgical Incise Drape PU 10x12 cm	47783	DU4540	HITEC Surgical Incise Drape PU 45x40 cm	47783
DU1020	HITEC Surgical Incise Drape PU 10x20 cm	47783	DU4545	HITEC Surgical Incise Drape PU 45x45 cm	47783
DU1030	HITEC Surgical Incise Drape PU 10x30 cm	47783	DU4548	HITEC Surgical Incise Drape PU 45x48 cm	47783
DU1050	HITEC Surgical Incise Drape PU 10x50 cm	47783	DU4555	HITEC Surgical Incise Drape PU 45x55 cm	47783
DU1060	HITEC Surgical Incise Drape PU 10x60 cm	47783	DU4560	HITEC Surgical Incise Drape PU 45x60 cm	47783
DU1520	HITEC Surgical Incise Drape PU 15x20 cm	47783	DU4565	HITEC Surgical Incise Drape PU 45x65 cm	47783
DU1528	HITEC Surgical Incise Drape PU 15x28 cm	47783	DU4590	HITEC Surgical Incise Drape PU 45x90 cm	47783
DU1530	HITEC Surgical Incise Drape PU 15x30 cm	47783	DU5045	HITEC Surgical Incise Drape PU 50x45 cm	47783
DU1620	HITEC Surgical Incise Drape PU 16x20 cm	47783	DU5060	HITEC Surgical Incise Drape PU 50x60 cm	47783
DU2010	HITEC Surgical Incise Drape PU 20x10 cm	47783	DU5545	HITEC Surgical Incise Drape PU 55x45 cm	47783
DU2020	HITEC Surgical Incise Drape PU 20x20 cm	47783	DU5580	HITEC Surgical Incise Drape PU 55x80 cm	47783
DU2030	HITEC Surgical Incise Drape PU 20x30 cm	47783	DU5640	HITEC Surgical Incise Drape PU 56x40 cm	47783
DU2040	HITEC Surgical Incise Drape PU 20x40 cm	47783	DU5645	HITEC Surgical Incise Drape PU 56x45 cm	47783
DU2815	HITEC Surgical Incise Drape PU 28x15 cm	47783	DU5660	HITEC Surgical Incise Drape PU 56x60 cm	47783
DU2830	HITEC Surgical Incise Drape PU 28x30 cm	47783	DU5680	HITEC Surgical Incise Drape PU 56x80 cm	47783
DU2840	HITEC Surgical Incise Drape PU 28x40 cm	47783	DU5685	HITEC Surgical Incise Drape PU 56x85 cm	47783
DU2845	HITEC Surgical Incise Drape PU 28x45 cm	47783	DU5690	HITEC Surgical Incise Drape PU 56x90 cm	47783
DU3020	HITEC Surgical Incise Drape PU 30x20 cm	47783	DU6030	HITEC Surgical Incise Drape PU 60x30 cm	47783
DU3027	HITEC Surgical Incise Drape PU 30x27 cm	47783	DU6035	HITEC Surgical Incise Drape PU 60x35 cm	47783
DU3030	HITEC Surgical Incise Drape PU 30x30 cm	47783	DU6040	HITEC Surgical Incise Drape PU 60x40 cm	47783
DU3035	HITEC Surgical Incise Drape PU 30x35 cm	47783	DU6045	HITEC Surgical Incise Drape PU 60x45 cm	47783
DU3040	HITEC Surgical Incise Drape PU 30x40 cm	47783	DU6050	HITEC Surgical Incise Drape PU 60x50 cm	47783
DU3045	HITEC Surgical Incise Drape PU 30x45 cm	47783	DU6055	HITEC Surgical Incise Drape PU 60x55 cm	47783
DU3050	HITEC Surgical Incise Drape PU 30x50 cm	47783	DU6060	HITEC Surgical Incise Drape PU 60x60 cm	47783
DU3060	HITEC Surgical Incise Drape PU 30x60 cm	47783	DU6070	HITEC Surgical Incise Drape PU 60x70 cm	47783
DU3535	HITEC Surgical Incise Drape PU 35x35 cm	47783	DU6080	HITEC Surgical Incise Drape PU 60x80 cm	47783
DU3540	HITEC Surgical Incise Drape PU 35x40 cm	47783	DU6085	HITEC Surgical Incise Drape PU 60x85 cm	47783
DU3545	HITEC Surgical Incise Drape PU 35x45 cm	47783	DU6090	HITEC Surgical Incise Drape PU 60x90 cm	47783
DU3550	HITEC Surgical Incise Drape PU 35x50 cm	47783	DU6640	HITEC Surgical Incise Drape PU 66x40 cm	47783

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DU3560	HITEC Surgical Incise Drape PU 35x60 cm	47783	DU6645	HITEC Surgical Incise Drape PU 66x45 cm	47783
DU4030	HITEC Surgical Incise Drape PU 40x30 cm	47783	DU6650	HITEC Surgical Incise Drape PU 66x50 cm	47783
DU4035	HITEC Surgical Incise Drape PU 40x35 cm	47783	DU6660	HITEC Surgical Incise Drape PU 66x60 cm	47783
DU4040	HITEC Surgical Incise Drape PU 40x40 cm	47783	DU6685	HITEC Surgical Incise Drape PU 66x85 cm	47783
DU4042	HITEC Surgical Incise Drape PU 40x42 cm	47783	DU6690	HITEC Surgical Incise Drape PU 66x90 cm	47783
DU4045	HITEC Surgical Incise Drape PU 40x45 cm	47783	DU9045	HITEC Surgical Incise Drape PU 90x45 cm	47783
DU4060	HITEC Surgical Incise Drape PU 40x60 cm	47783	DU9050	HITEC Surgical Incise Drape PU 90x50 cm	47783
DU4528	HITEC Surgical Incise Drape PU 45x28 cm	47783	DU9060	HITEC Surgical Incise Drape PU 90x60 cm	47783
DU4530	HITEC Surgical Incise Drape PU 45x30 cm	47783			

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Comerț-Magor S.R.L.**, cu sediul în **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip Dispozitiv	Cod GMDN	Clasa de risc
ID6040	Cimp de incizie	HITEC ID6040	60x40cm	SURGICAL INCISE DRAPE	47783	Clasa Is

Sunt autentice și corespund realității.

Administrator Cojocaru Vladimir *Semnătura* _____

Data 17.09.2023

Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. **27** din **17.09.2023**

Solicitantul **Comerț-Magor S.R.L.**, cu sediul **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, tel./fax: **022742200/022743931**, e-mail **veracojocaru@mail.ru**, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip Dispozitiv	Cod GMDN	Clasa de risc
ID6040	Cimp de incizie	HITEC ID6040	60x40cm	SURGICAL INCISE DRAPE	47783	Clasa Is

Se anexează următoarele acte:

a) declarația de conformitate CE emisă de producător pentru dispozitivele fabricate
b) certificatul de calitate CE valabil pentru dispozitivele fabricate
c) actul prin care producătorul își desemnează reprezentantul

Data **17.09.2023** 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	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

AUTHORIZATION LETTER

Subject: Distribution in **Moldova**

Date: 13 September 2023

To Whom It May Concern;

This is to inform you that,

COMERŢ-MAGOR S.R.L.
str. Bucuriei 1, MD-2004, Chisinau, Republic of Moldova
1003600022518

has been appointed as representative in Moldova for Surgical Mesh and Surgical Incision Drapes, which are manufactured by Klas Medikal and thus are allowed to register, distribute, promote, exhibit and submit/quote for tenders in territory of Moldova on behalf of manufacturer company:

Klas Medikal Cih. San. Müm. İç Ve Dış Tic Ltd Şti.,
Ramazanoğlu Mahallesi, Mahsus Sokak No:1
Pendik, İstanbul Turkey

COMERŢ-MAGOR S.R.L. is responsible for all their actions in regard to Agency of Medicine and Medical Devices Authority activities and all tenders in Moldova.

This Authorization Letter starts at 13 September 2023 and expires on 31 December 2026 unless any new authorization letter or cancellation letter is issued afterwards.

Sincerely yours,

Foreign Trade Manager

KLAS MEDİKAL CİHAZLAR SANAYİ
MÜMESSİLLİK İÇ VE DIŞ TİC. LTD. ŞTİ.
Ramazanoğlu Mah. Mahsus Sok. No:1
Pendik / İstanbul
V.D. : PENDİK V.N. : 564 028 4327
Ticaret Sicil No : 473286
Tel: 0216 576 4 888 Fax: 0216 577 82 97