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Date: 2019.02.14 17:30:43 IST
Reason: MoldSign Signature
Location: Moldova



REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII

Nr. 044322

Denumirea autorității de licențiere

Camera de Licențiere

Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență

**Societatea cu Răspundere Limitată
"BIOSISTEM MLD"**

mun. Chișinău, str. Albișoara, 16/1, ap. 7

Data și numărul certificatului de înregistrare de stat a titularului de licență

12.08.2010 MD 0101250

Numărul de înregistrare a întreprinderii sau IDNO

1010600028048

Codul fiscal

Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența

*** Importul, comercializarea, asistența tehnică și reparația dispozitivelor medicale ***

Data eliberării licenței

4 octombrie 2010

Reperfectată: 1)19.10.2012; 2)14.05.2014

Valabilă pînă la

4 octombrie 2015

Prelungită pînă la: 03.10.2020

**Semnătura conducătorului
autorității de licențiere**

Director al Camerei de Licențiere

Valentin GUZNAC



Notă: Licența este valabilă numai cu anexa autenticată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.



BC "MOLDINDCONBANK" S.A. Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московской, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent
in moneda nationala al “BIOSISTEM MLD” S.R.L. (c/f 1010600028048), cu
IBAN MD95ML000000002251429243.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

L. Svirepova
semnătura

MD 0101250





„CAMERA ÎNREGISTRĂRII DE STAT” Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 14419 din 11.07.2016

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: «BIOSISTEM MLD» S.R.L.

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE, IDNP 0983103892591,

Asociați:

- 1. POIATA VITALIE , IDNP 0983103892591**
cota 1803.60 lei, ce constituie 33,4 %
- 2. NASEDCHIN ALEXANDR , IDNP 2002001070747**
cota 1798.20 lei, ce constituie 33,3 %
- 3. KOJEVNIKOV DMITRII , IDNP 0972305012362**
cota 1798.20 lei, ce constituie 33,3 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 11.07.2016.

Specialist principal
tel. 022-266-252


Lazari Aliona



Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandru Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2017 31.12.2017

Entitatea BIOSISTEM MLD SRL
(Denumirea completă)40717392
(Cod CUIIO)1010600028048
(Cod IDNO)Sediul: MD MD-2001 MUN.CHIȘINĂU; MUN.CHIȘINĂU SEC.RÎȘCANI 150
(Cod poștal) Raionul (municipiul, UTA); Localitatea Albisoara, 16, 1, of.7 Cod CUATMActivitatea principală: strada, nr, bl. Comert cu ridicata al produselor farmaceutice
G4646
Cod CAEM, rev.2Forma de proprietate: Proprietate privată 15
Cod CFPForma organizatorico-juridică: SOCIETATI CU RASPUNDERE LIMITATA 530
Cod CFOJDate de contact: Tel. +37322808719 e-mail biosistem.mld@gmail.com
WEB:Numele și coordonatele al contabilului-șef: Dl (dna) +37322808719 Unitatea de măsură: leu
Tel. +37369463619

Anexa 8

Notă informativă privind veniturile și cheltuielile clasificate după natură

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vânzări	010	15.623.709	20.497.176
Alte venituri din activitatea operațională	020		500
Venituri din alte activități	030	368.943	361.872
Total venituri (rd.010 + rd.020 + rd.030)	040	15.992.652	20.859.548
Variația stocurilor	050		
Costul vânzărilor	060	9.960.221	11.372.168
Cheltuieli privind stocurile	070	306.856	118.975
Cheltuieli cu personalul privind remunerarea muncii	080	129.850	169.200
Contribuții de asigurări sociale de stat obligatorii și prime de asigurare obligatorie de asistență medicală	090	35.709	46.530
Cheltuieli cu amortizarea și deprecierea activelor imobilizate	100	7.389	90.494
Alte cheltuieli	110	306.855	548.183
Cheltuieli din alte activități	120	289.432	558.776
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	11.036.312	12.904.326
Profit (pierdere) pînă la impozitare (rd.040 – rd.130)	140	4.956.340	7.955.222
Cheltuieli privind impozitul pe venit	150	595.238	959.194
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160	4.361.102	6.996.028

BILANȚUL

Anexa 1

la 31.12.2017

Nr. crt.	ACTIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
1.	Active imobilizate			
	Imobilizări necorporale	010	2.437	1.787
	Imobilizări corporale în curs de execuție	020		
	Terenuri	030		
	Mijloace fixe	040	195.525	904.703
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investiții financiare pe termen lung în părți neafiliate	070		
	Investiții financiare pe termen lung în părți afiliate	080		
	Investiții imobiliare	090		
	Creanțe pe termen lung	100		
	Avansuri acordate pe termen lung	110		
	Alte active imobilizate	120		
	Total active imobilizate (rd.010 + rd.020 + rd.030 + rd.040 + rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	197.962	906.490
2.	Active circulante			
	Material	140	2.329	457
	Active biologice circulante	150		
	Obiecte de mică valoare și scurtă durată	160	49.454	63.968
	Producția în curs de execuție și produse	170		
	Mărfuri	180	3.435.875	4.430.031
	Creanțe comerciale	190	5.303.786	3.157.174
	Creanțe ale părților afiliate	200		
	Avansuri acordate curente	210	793.582	1.097.547
	Creanțe ale bugetului	220	35.037	4.973
	Creanțe ale personalului	230		
	Alte creanțe curente	240		
	Numerar în casierie și la conturi curente	250	747.829	4.742.040
	Alte elemente de numerar	260		
	Investiții financiare curente în părți neafiliate	270		
	Investiții financiare curente în părți afiliate	280		
	Alte active circulante	290	8.004	5.373
	Total active circulante (rd.140 + rd.150 + rd.160 + rd.170 + rd.180 + rd.190 + rd.200 + rd.210 + rd.220 + rd.230 + rd.240 + rd.250 + rd.260 + rd.270 + rd.280 + rd.290)	300	10.375.896	13.501.563
	Total active (rd.130 + rd.300)	310	10.573.858	14.408.053

Nr. crt.	PASIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
3.	Capital propriu			
	Capital social și suplimentar	320	5.400	5.400
	Rezerve	330		
	Corecții ale rezultatelor anilor precedenți	340	X	
	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	350		
	Profit net (pierdere netă) al perioadei de gestiune	360	8.952.137	5.643.627
	Profit utilizat al perioadei de gestiune	370	X	6.996.028
	Alte elemente de capital propriu	380		
	Total capital propriu (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 + rd.370 + rd.380)	390	8.957.537	12.645.055
4.	Datorii pe termen lung			
	Credite bancare pe termen lung	400		
	Împrumuturi pe termen lung	410		
	Datorii pe termen lung privind leasingul financiar	420		
	Alte datorii pe termen lung	430		
	Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)	440		
5.	Datorii curente			
	Credite bancare pe termen scurt	450		
	Împrumuturi pe termen scurt	460		
	Datorii comerciale	470	1.084.518	1.595.609
	Datorii față de părțile afiliate	480		
	Avansuri primite curente	490	186.214	7.303
	Datorii față de personal	500	7.343	45.149
	Datorii privind asigurările sociale și medicale	510		
	Datorii față de buget	520	318.484	39.698
	Venituri anticipate curente	530		
	Datorii față de proprietari	540		
	Finanțări și încasări cu destinație specială curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	19.762	75.239
	Total datorii curente (rd.450 + rd.460 + rd.470 + rd.480 + rd.490 + rd.500 + rd.510 + rd.520 + rd.530 + rd.540 + rd.550 + rd.560 + rd.570)	580	1.616.321	1.762.998
	Total pasive (rd.390 + rd.440 + rd.580)	590	10.573.858	14.408.053

SITUAȚIA DE PROFIT ȘI PIERDERE

Anexa 2

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vânzări	010	15.623.709	20.497.176
Costul vânzării	020	9.960.221	11.372.168
Profit brut (pierdere brută) (rd.010 - rd.020)	030	5.663.488	9.125.008
Alte venituri din activitatea operațională	040		500
Cheltuieli de distribuție	050	208	202
Cheltuieli administrative	060	513.937	622.704
Alte cheltuieli din activitatea operațională	070	272.514	350.476
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	4.876.829	8.152.126
Rezultatul din alte activități: profit (pierdere)	090	79.511	-196.904
Profit (pierdere) pînă la impozitare (rd.080 + rd.090)	100	4.956.340	7.955.222
Cheltuieli privind impozitul pe venit	110	595.238	959.194
Profit net (pierdere netă) al perioadei de gestiune (rd.100 - rd.110)	120	4.361.102	6.996.028

SITUAȚIA MODIFICĂRII CAPITALULUI PROPRIU

Anexa 3

de la 01.01.2017 pînă la 31.12.2017

Nr. /No.	Indicatori	Cod rd.	Sold la			
			Începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfârșitul perioadei de gestiune
1	2	3	4	5	6	7
1.	Capital social și suplimentar					
	Capital social	010	5.400			5.400
	Capital suplimentar	020				
	Capital nevărsat	030	0	0	0	0
	Capital netregistrat	040				
	Capital retras	050	0	0	0	0
	Total capital social și suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5.400			5.400
2.	Rezerve					
	Capital de rezervă	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total rezerve (rd.070 + rd.080 + rd.090)	100				
3.	Profit nerepartizat (pierdere neacoperită)					
	Corecții ale rezultatelor anilor precedenți	110				
	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	120	8.952.137	4.361.103	7.609.613	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	130	X	5.996.028		6.996.028
	Profit utilizat al perioadei de gestiune	140	X	0	0	0
	Rezultatul din tranziția la noile reglementări contabile	150				
	Total profit nerepartizat (pierdere neacoperită) (rd.110 + rd.120 + rd.130 + rd.140 + rd.150)	160	8.952.137	11.357.131	7.609.613	12.639.655
4.	Alte elemente de capital propriu, din care					
	Diferențe din reevaluare	171				
	Subvenții entităților cu proprietate publică	172				

Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180	8.957.537	11.357.131	7.609.613	12.645.055
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SITUAȚIA FLUXURILOR DE NUMERAR

Anexa 4

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010	16.364.220	30.547.593
Plăți pentru stocuri și servicii procurate	020	18.057.882	1.242.716
Plăți către angajați și organe de asigurare socială și medicală	030	165.559	205.235
Dobânzi plătite	040		
Plata impozitului pe venit	050	359.402	1.213.720
Alte încasări	060	2.173.630	
Alte plăți	070	647.102	20.861.222
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	-692.095	7.024.700
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobânzi încasate	110		
Dividende încasate	120		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 + rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170	1.127.660	3.110.000
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 + rd.170 + rd.180 + rd.190)	200	-1.127.660	-3.110.000
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	-1.819.755	3.914.700
Diferențe de curs valutar favorabile (nefavorabile)	220	79.511	79.511
Sold de numerar la începutul perioadei de gestiune	230	2.488.073	747.829
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	747.829	4.742.040

Date generale

1. Certificat de înregistrare a entității, eliberat de Camera înregistrării de Stat.
 Număr de înregistrare MD0101250, Data înregistrării 12.08.2014, Seria MD, Număr 0101250
2. Capital social înregistrat de Camera înregistrării de Stat:
 data 12.08.2010, suma 5.400 lei, inclusiv:
 1) cota statului _____ lei,
 2) cota deținătorilor a cel puțin 20% _____ lei.
 Modificări ulterioare:
 a) _____, suma _____ lei, inclusiv cota statului _____ lei,
 b) _____, suma _____ lei, inclusiv cota statului _____ lei.
3. Entitățile, activitatea cărora necesită licență, indică:
 Licența în vigoare:
 1) Număr 044322, data eliberării 2010-10-04 00:00:00
 Termen de valabilitate 03.10.2020
 Tipul de activitate _____
 Organul care a eliberat licența _____
4. Numărul mediu scriptic al personalului în perioada de gestiune _____ persoane, inclusiv pe categorii:
 1) personal administrativ _____ persoane,
 2) muncitori _____ persoane.
5. Numărul personalului la 31.12.2017 _____ persoane
6. Remunerarea personalului entității în perioada de gestiune _____ lei
7. Remunerarea membrilor organelor de administrare, de conducere și supraveghere și alte angajamente apărute sau asumate în legătură cu pensiile membrilor actuali sau ale foștilor membri ai acestor organe, pe categorii _____ lei
8. Avansurile și creditele acordate membrilor organelor specificate la pct.7 _____ lei, inclusiv rambursate _____ lei.
9. Valoarea activelor imobilizate și circulante, înregistrate în calitate de gaj:¹
 1) valoarea de gaj _____ lei,
 2) valoarea contabilă _____ lei.
10. Numărul acțiunilor ordinare la finele perioadei de gestiune _____ unități.
11. Profit net (pierdere netă) a perioadei de gestiune pentru o acțiune ordinară:
 1) profit _____ lei,
 2) pierdere _____ lei.
12. Dividende calculate pentru o acțiune ordinară pentru perioada de gestiune:
 1) plătite _____ lei,
 2) planificate pentru plată _____ lei.
13. Valută străină disponibilă, recalculată în monedă națională a Republicii Moldova – total 849.462 lei, inclusiv (lei, denumirea și codul valutei):
 1) 698537 codul valutei Euro
 2) 150925 codul valutei US Dollar

14. Numerar legat – total _____ lei.

În rîndurile, în care se înscriu sumele de gaj, în toate coloanele prin fracție se reflectă:
 a) la numărător – valoarea de gaj;
 b) la numitor – valoarea contabilă

Anexa 7

Informațiile privind activele imobilizate
de la 01.01.2017, până la 31.12.2017

Indicatori	Nr. rînd	Existența la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieșirea în cursul perioadei (la costul de intrare)	Existența la sfîrșitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrșitul perioadei	Deprecierea acumulată la sfîrșitul perioadei
		2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuție	10C								
2. Imobilizări corporale în utilizare, total inclusiv:	20C	3.25C	81.3				3.25C	1.463	
2.1. brevete și mărci	21C								
2.2. licențe de activitate	22C	3.25C	81.3				3.25C	1.463	
2.3. programe informatice	23C								
3. Imobilizări corporale în curs de execuție	30C								
4. Terenuri	40C		X					X	
5. Mijloace fixe, total din care:	500	205.204	9.679		796.422	6.100	995.526	90.823	
5.1. clădiri	51C								
5.2. construcții speciale	52C								
5.3. mașini, utilaje, instalații de transmisie inclusiv: tehnică de calcul	53C	186.815	8.908		796.422	6.100	971.141	85.929	
5.4. mijloace de transport	54C								
5.5. instrumente și inventar	55C								
5.6. costuri aferente obiectelor neînregistrate în bilanț	56C								
5.7. mijloace fixe primite în leasing financiar	57C								
5.8. mijloace fixe primite în gestiune economică	58C								
5.9. alte mijloace fixe	59C	18.385	1.379				18.385	6.894	
6. Resurse minerale	600								
7. Investiții imobiliare, total	700								

Recipisa de primire a raportului

ID-ul raportului 289272
 Tipul raportului RSF1
 Tipul perioadei de raportare Anual
 Anul de raportare 2017
 Numărul de raportare a perioadei (număr) 10
 Numărul de raportare a perioadei (text) an
 Codul statistic al organizației 40717392
 Codul fiscal al organizației 1010600028048
 IDNO organizației 1010600028048
 Denumirea organizației BIOSISTEM MLD SRL
 Statutul raportului Primit la BNS
 Data creării raportului 26.03.2018 11:08:42
 Data expedierii raportului 27.03.2018 13:54:13
 Subdiviziunea teritorială a BNS mun. Chișinău
 Telefonul subdiviziunii teritoriale a BNS 0-22-739581

Таблицы финансового отчёта автоматически проверены на арифметические ошибки и логические связи между таблицами.

Контроль показателей на соответствие с предыдущим финансовым отчётом на данный момент НЕ выполнен.

Ответственность за правильность отражения экономических операций в бухгалтерском учёте и применённых методов учёта, а также за достоверность и полноту представленных данных и приложений несёт субъект и его ответственные лица, подписавшие финансовые отчёты.

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A1906045**

din
от **08.02.2019**

1. Destinatar / Получатель

Pentru participarea la proceduri de achiziții publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

**3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /
Подтверждение отсутствия или наличия недоимки согласно данных Автоматизированной Информационной Системы**

La data emiterii prezentului certificat restanța la bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:
0,00 lei/лей.

4. Valabil pînă la / Действителен до 23.02.2019

5. Autentificarea organului fiscal / Подтверждение налогового органа

Sef. Serv. Riscani
Funcția/Dолжность



Semnătura/Подпись

Suo Hoicor
Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor:

Uroian C
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 08.02.2019 ora 16:43:41
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (2,21)



C E R T I F I C A T E

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

M.2016.106.6949-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : Betatech Medikal Cihazlar Sanayi Mmssillik İ ve Dış Tic. Ltd. Şti.

Company Address : İki Telli Organize Sanayi Bölgesi Atatrk Oto Sanayi Sitesi, 22 Sok.
nal İş Merkezi No:9 Başakşehir İSTANBUL / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II
(Excluding Section 4)

Product : Neurosurgical Patty - Class III
- Radiopaque, with thread
- Radiopaque, without thread
Partially Absorbable Composite Mesh - Class III
- Polymesh Composite
- Polymesh Inova
Absorbable Hemostat Oxidized Regenerated Cellulose - Class III
Dual Side Surgical Mesh - Class IIb
Surgical Mesh for Hernia and Pelvic Surgery - Class IIb
Adhesion Barrier Gel - Class III

Certificate Number : M.2016.106.6949

Report Number : MD.3135.IB

Initial Assessment Date : 20.05.2016

Registration Date : 25.08.2016

Revision Date /No : 23.11.2016/01

Expiry Date : 24.08.2021


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

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex 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. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through www.udemltd.com.tr.

CE
2292



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.udemltd.com.tr



THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
(Turkish Medicines and Medical Devices Agency)

Date of issue : 15 February 2017

TO WHOM IT MAY CONCERN

HEALTH CERTIFICATE
Free Sales Certificate

Medical devices, which are in the scope of Medical Devices Directives, listed additional page(s), produced by the manufacturer called "BETATECH MEDİKAL CİHAZLAR SANAYİ MÜMESSİLLİK İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ (İkitelli Org.San.Blg. Atatürk Oto San. Sit.Ünal İş Mrk. 22. Sok. No:9 Başakşehir / İstanbul / TÜRKİYE)" is freely sold in Turkey and European Union and exported to other countries.

This certificate expires after 36 months from the date of issue.

Sincerely Yours

Yalçın SOYSAL, MD.
Head of Medical Device Department



Turkish Medicines and Medical Devices Agency 06520 Çankaya-Ankara-TÜRKİYE

Phone: +90 312 218 30 00 Fax: +90 312 218 30 59

Note: Please determine the section code, reference number and date in your answers <http://www.titck.gov.tr>

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PRODUCT LIST

Barcode	Label Name	Trade Name	GMDN Code	Ref. Number
8699409033355	Dual Side Surgical Mesh 11cm	POLYMESH	16048	SDMO11
8699409033249	Partially Absorbable Composite Mesh 20x30cm	POLYMESH	16048	SCM2030
8699409034789	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 7.5 cm x 10 cm	OXICEL	35895	OXS19
8699409033935	Neurosurgical Patty - COT 25x75 mm	BETAMIX	13702	CNS2575
8699409033171	Partially Absorbable Composite Mesh Ventral 4,3x4,3cm	POLYMESH	16048	SCMV1
8699409034215	Neurosurgical Patty - SOFT 10x10 mm	BETAMIX	13702	SNS1010
8699409034352	Neurosurgical Patty - SOFT 25x25 mm	BETAMIX	13702	SNS2525
8699409030200	Surgical Mesh 20x30cm	POLYMESH	16048	PM2030
8699409034079	Neurosurgical Patty - ULTRACOT 12x50 mm	BETAMIX	13702	UNS1250
8699409030156	Surgical Mesh 15x30cm	POLYMESH	16048	PM1530
8699409034222	Neurosurgical Patty - SOFT 10x20 mm	BETAMIX	13702	SNS1020
8699409035304	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 5 cm x 7,5 cm	OXICEL	35895	OXS25
8699409034871	Absorbable Hemostat Oxidized Regenerated Cellulose Knit 2.5 cm x 5.1 cm	OXICEL	35895	OXK14
8699409031795	Dual Side Surgical Mesh 20x20cm	POLYMESH	16048	SDM2020
8699409034581	Neurosurgical Patty - PURECOTTON 25x50 mm	BETAMIX	13702	PNS2550
8699409030019	Surgical Mesh 6x14cm	POLYMESH	16048	PM614
8699409031788	Dual Side Surgical Mesh 15x20cm	POLYMESH	16048	SDM1520
8699409033157	Partially Absorbable Composite Mesh plug 11cm	POLYMESH	16048	SCMP11
8699409034154	Neurosurgical Patty - ULTRACOT 25x75 mm	BETAMIX	13702	UNS2575
8699409034253	Neurosurgical Patty - SOFT 10x75 mm	BETAMIX	13702	SNS1075
8699409033096	Adhesion Barrier Gel 4 ml	BETAMIX	34212	ABGT04
8699409034512	Neurosurgical Patty - PURECOTTON 12x50 mm	BETAMIX	13702	PNS1250
8699409034482	Neurosurgical Patty - PURECOTTON 12,5x12,5 mm	BETAMIX	13702	PNS1212
8699409033317	Dual Side Surgical Mesh 30x30cm	POLYMESH	16048	SDM3030
8699409031894	Dual Side Surgical Mesh plug 11cm	POLYMESH	16048	SDMP11
8699409033195	Partially Absorbable Composite Mesh Ventral 8x8cm	POLYMESH	16048	SCMV3
8699409033225	Partially Absorbable Composite Mesh 10x15cm	POLYMESH	16048	SCM1015
8699409034321	Neurosurgical Patty - SOFT 20x40 mm	BETAMIX	13702	SNS2040
8699409034239	Neurosurgical Patty - SOFT 10x30 mm	BETAMIX	13702	SNS1030
8699409031887	Dual Side Surgical Mesh plug 09cm	POLYMESH	16048	SDMP09
8699409033287	Dual Side Surgical Mesh plug 09cm	POLYMESH	16048	SDMP09
8699409034918	Absorbable Hemostat Oxidized Regenerated Cellulose Fibril 2.6 cm x 2.6 cm	OXICEL	35895	OXF11
8699409032129	Partially Absorbable Composite Mesh 11cm	POLYMESH	16048	SCMO11
8699409032044	Partially Absorbable Composite Mesh 7,5x15cm	POLYMESH	16048	SCM7515
8699409030088	Surgical Mesh 8x13cm	POLYMESH	16048	PM813
8699409033409	Dual Side Surgical Mesh 10x15cm	POLYMESH	16048	SDM1015
8699409034444	Adhesion Barrier Gel 3,5 ml	BETAMIX	34212	ABG305
8699409033782	Neurosurgical Patty - COT 10x20 mm	BETAMIX	13702	CNS1020
8699409031832	Dual Side Surgical Mesh 30x30cm	POLYMESH	16048	SDM3030
8699409033218	Partially Absorbable Composite Mesh plug 07cm	POLYMESH	16048	SCMP07
8699409032075	Partially Absorbable Composite Mesh 15x15cm	POLYMESH	16048	SCM1515
8699409034611	Neurosurgical Patty - PURECOTTON 40x50 mm	BETAMIX	13702	PNS4050
8699409034451	Adhesion Barrier Gel 4,5 ml	BETAMIX	34212	ABG405
8699409034772	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 5.1 cm x 35.6 cm	OXICEL	35895	OXS18
8699409033447	Dual Side Surgical Mesh 6x11cm	POLYMESH	16048	SDM0611
8699409034000	Neurosurgical Patty - ULTRACOT 10x20 mm	BETAMIX	13702	UNS1020
8699409033126	Partially Absorbable Composite Mesh 8x14cm	POLYMESH	16048	SCM0814
8699409034260	Neurosurgical Patty - SOFT 12x12 mm	BETAMIX	13702	SNS1212
8699409035656	Neurosurgical Patty - SOFT 20x60 mm	BETAMIX	13702	SNS2060
8699409034062	Neurosurgical Patty - ULTRACOT 12x40 mm	BETAMIX	13702	UNS1240
8699409034673	Neurosurgical Patty - PURECOTTON 10x30 mm	BETAMIX	13702	PNS1030

Yalçın SOYSAL, MD.
Head of Medical Device Department

PRODUCT LIST

Barcode	Label Name	Trade Name	GMDN Code	Ref. Number
8699409034635	Neurosurgical Patty - PURECOTTON 70x70 mm	BETAMIX	13702	PNS7070
8699409033461	Dual Side Surgical Mesh 26x34cm	POLYMESH	16048	SDM2634
8699409035694	Neurosurgical Patty - ULTRACOT 10x15 mm	BETAMIX	13702	UNS1015
8699409030118	Surgical Mesh 14x9cm	POLYMESH	16048	PM149
8699409033874	Neurosurgical Patty - COT 20x20 mm	BETAMIX	13702	CNS2020
8699409034529	Neurosurgical Patty - PURECOTTON 12x75 mm	BETAMIX	13702	PNS1275
8699409033331	Dual Side Surgical Mesh 25x35cm	POLYMESH	16048	SDM2535
8699409032150	Partially Absorbable Composite Mesh plug 09cm	POLYMESH	16048	SCMP09
8699409031863	Dual Side Surgical Mesh 15cm	POLYMESH	16048	SDMO15
8699409034024	Neurosurgical Patty - ULTRACOT 10x40 mm	BETAMIX	13702	UNS1040
8699409031849	Dual Side Surgical Mesh 10x15/22cm	POLYMESH	16048	SDM1022
8699409034338	Neurosurgical Patty - SOFT 20x70 mm	BETAMIX	13702	SNS2070
8699409034093	Neurosurgical Patty - ULTRACOT 20x20 mm	BETAMIX	13702	UNS2020
8699409033928	Neurosurgical Patty - COT 25x50 mm	BETAMIX	13702	CNS2550
8699409034567	Neurosurgical Patty - PURECOTTON 20x90 mm	BETAMIX	13702	PNS2090
8699409032051	Partially Absorbable Composite Mesh 10x12cm	POLYMESH	16048	SCM1012
8699409033119	Partially Absorbable Composite Mesh 11cm	POLYMESH	16048	SCMO11
8699409034574	Neurosurgical Patty - PURECOTTON 25x25 mm	BETAMIX	13702	PNS2525
8699409033393	Dual Side Surgical Mesh 7,5x15cm	POLYMESH	16048	SDM715
8699409033188	Partially Absorbable Composite Mesh 20x20cm	POLYMESH	16048	SCM2020
8699409033904	Neurosurgical Patty - COT 20x90 mm	BETAMIX	13702	CNS2090
8699409035366	Neurosurgical Patty - SOFT 12,5x25 mm	BETAMIX	13702	SNS1225
8699409034345	Neurosurgical Patty - SOFT 20x90 mm	BETAMIX	13702	SNS2090
8699409034086	Neurosurgical Patty - ULTRACOT 12x75 mm	BETAMIX	13702	UNS1275
8699409034376	Neurosurgical Patty - SOFT 25x75 mm	BETAMIX	13702	SNS2575
8699409034680	Neurosurgical Patty - PURECOTTON 10x40 mm	BETAMIX	13702	PNS1040
8699409034420	Adhesion Barrier Gel 1,5 ml	BETAMIX	34212	ABG105
8699409034598	Neurosurgical Patty - PURECOTTON 25x75 mm	BETAMIX	13702	PNS2575
8699409034956	Absorbable Hemostat Oxidized Regenerated Cellulose Fibril 5.1 cm x 10.2 cm	OXICEL	35895	OXF15
8699409034703	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 1.25 cm x 5 cm	OXICEL	35895	OXS11
8699409030194	Surgical Mesh 30x30cm	POLYMESH	16048	PM3030
8699409034970	Absorbable Hemostat Oxidized Regenerated Cellulose Fibril 5 cm x 7.5 cm	OXICEL	35895	OXF17
8699409033232	Partially Absorbable Composite Mesh 15x20cm	POLYMESH	16048	SCM1520
8699409034642	Neurosurgical Patty - PURECOTTON 05x05 mm	BETAMIX	13702	PNS0505
8699409034796	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 10 cm x 20 cm	OXICEL	35895	OXS20
8699409030033	Surgical Mesh 7,5x15cm	POLYMESH	16048	PM7515
8699409034284	Neurosurgical Patty - SOFT 12x40 mm	BETAMIX	13702	SNS1240
8699409033942	Neurosurgical Patty - COT 40x40 mm	BETAMIX	13702	CNS4040
8699409034833	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 5 cm x 10 cm	OXICEL	35895	OXS24
8699409034277	Neurosurgical Patty - SOFT 12x25 mm	BETAMIX	13702	SNS1225
8699409032006	Partially Absorbable Composite Mesh 5x8cm	POLYMESH	16048	SCM0508
8699409030378	Pelvic Organ Prolapse Mesh-6 Arms	BETAMIX	35259	BTMN11
8699409034741	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 2.5 cm x 5 cm	OXICEL	35895	OXS15
8699409033324	Dual Side Surgical Mesh 10x15/22cm	POLYMESH	16048	SDM1022
8699409034543	Neurosurgical Patty - PURECOTTON 20x40 mm	BETAMIX	13702	PNS2040
8699409033805	Neurosurgical Patty - COT 10x40 mm	BETAMIX	13702	CNS1040
8699409034659	Neurosurgical Patty - PURECOTTON 10x10 mm	BETAMIX	13702	PNS1010
8699409034925	Absorbable Hemostat Oxidized Regenerated Cellulose Fibril 7.6 cm x 10.2 cm	OXICEL	35895	OXF12
8699409034406	Neurosurgical Patty - SOFT 40x70 mm	BETAMIX	13702	SNS4070

Yalçın SOYSAL, MD.
Head of Medical Device Department

PRODUCT LIST

Barcode	Label Name	Trade Name	GMDN Code	Ref. Number
8699409034949	Absorbable Hemostat Oxidized Regenerated Cellulose Fibril 2.5 cm x 5.1 cm	OXICEL	35895	OXF14
8699409033201	Partially Absorbable Composite Mesh 30x30cm	POLYMESH	16048	SCM3030
8699409033478	Dual Side Surgical Mesh 6x14cm	POLYMESH	16048	SDM0614
8699409034383	Neurosurgical Patty - SOFT 40x40 mm	BETAMIX	13702	SNS4040
8699409033386	Dual Side Surgical Mesh 7x12cm	POLYMESH	16048	SDM0712
8699409033881	Neurosurgical Patty - COT 20x40 mm	BETAMIX	13702	CNS2040
8699409033140	Partially Absorbable Composite Mesh 15x15cm	POLYMESH	16048	SCM1515
8699409034031	Neurosurgical Patty - ULTRACOT 10x75 mm	BETAMIX	13702	UNS1075
8699409034734	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 2.5 x 2.5 cm	OXICEL	35895	OXS14
8699409033270	Dual Side Surgical Mesh 15x20cm	POLYMESH	16048	SDM1520
8699409034697	Partially Absorbable Composite Mesh 10x12cm	POLYMESH	16048	SCM1012
8699409033362	Dual Side Surgical Mesh 20x30cm	POLYMESH	16048	SDM2030
8699409031801	Dual Side Surgical Mesh 20x30cm	POLYMESH	16048	SDM2030
8699409032167	Partially Absorbable Composite Mesh plug 1cm	POLYMESH	16048	SCMP11
8699409033379	Dual Side Surgical Mesh 15x15cm	POLYMESH	16048	SDM1515
8699409031771	Dual Side Surgical Mesh 15x15cm	POLYMESH	16048	SDM1515
8699409034314	Neurosurgical Patty - SOFT 20x20 mm	BETAMIX	13702	SNS2020
8699409030101	Surgical Mesh 10x15cm	POLYMESH	16048	PM1015
8699409030170	Surgical Mesh 20x20cm	POLYMESH	16048	PM2020
8699409034130	Neurosurgical Patty - ULTRACOT 25x25 mm	BETAMIX	13702	UNS2525
8699409034147	Neurosurgical Patty - ULTRACOT 25x50 mm	BETAMIX	13702	UNS2550
8699409032952	Adhesion Barrier Gel 15ml	BETAMIX	34212	ABGNS15
8699409031733	Dual Side Surgical Mesh 7x12cm	POLYMESH	16048	SDM0712
8699409034901	Absorbable Hemostat Oxidized Regenerated Cellulose Knit 5 cm x 7.5 cm	OXICEL	35895	OXK17
8699409033430	Dual Side Surgical Mesh 8x14cm	POLYMESH	16048	SDM0814
8699409033980	Neurosurgical Patty - ULTRACOT 5x5 mm	BETAMIX	13702	UNS55
8699409034499	Neurosurgical Patty - PURECOTTON 12x25 mm	BETAMIX	13702	PNS1225
8699409033423	Dual Side Surgical Mesh R12cm	POLYMESH	16048	SDMR12
8699409033867	Neurosurgical Patty - COT 12x75 mm	BETAMIX	13702	CNS1275
8699409034727	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 1.5 x 5 cm	OXICEL	35895	OXS13
8699409033263	Partially Absorbable Composite Mesh 7x12cm	POLYMESH	16048	SCM0712
8699409032013	Partially Absorbable Composite Mesh 6x1cm	POLYMESH	16048	SCM0611
8699409034390	Neurosurgical Patty - SOFT 40x50 mm	BETAMIX	13702	SNS4050
8699409031818	Dual Side Surgical Mesh 25x35cm	POLYMESH	16048	SDM2535
8699409034246	Neurosurgical Patty - SOFT 10x40 mm	BETAMIX	13702	SNS1040
8699409030682	Adhesion Barrier Gel 20ml	BETAMIX	34212	ABG20
8699409033454	Dual Side Surgical Mesh plug 07cm	POLYMESH	16048	SDMP07
8699409030637	Adhesion Barrier Gel 3ml	BETAMIX	34212	ABG03
8699409034192	Neurosurgical Patty - ULTRACOT 70x70 mm	BETAMIX	13702	UNS7070
8699409034505	Neurosurgical Patty - PURECOTTON 12x40 mm	BETAMIX	13702	PNS1240
8699409034895	Absorbable Hemostat Oxidized Regenerated Cellulose Knit 10.2 cm x 10.2 cm	OXICEL	35895	OXK16
8699409033089	Adhesion Barrier Gel 1 ml	BETAMIX	34212	ABGT01
8699409034178	Neurosurgical Patty - ULTRACOT 40x50 mm	BETAMIX	13702	UNS4050
8699409030040	Surgical Mesh 8x15cm	POLYMESH	16048	PM815
8699409033775	Neurosurgical Patty - COT 10x10 mm	BETAMIX	13702	CNS1010
8699409034802	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 10.2 cm x 20.3 cm	OXICEL	35895	OXS21
8699409034468	Adhesion Barrier Gel 7,5 ml	BETAMIX	34212	ABG705
8699409034857	Absorbable Hemostat Oxidized Regenerated Cellulose Knit 7.6 cm x 10.2 cm	OXICEL	35895	OXK12
8699409034109	Neurosurgical Patty - ULTRACOT 20x40 mm	BETAMIX	13702	UNS2040
8699409032099	Partially Absorbable Composite Mesh 20x20cm	POLYMESH	16048	SCM2020

Yalçın SOYSAL, MD.
Head of Medical Device Department

PRODUCT LIST

Barcode	Label Name	Trade Name	GMDN Code	Ref. Number
8699409034185	Neurosurgical Patty - ULTRACOT 40x70 mm	BETAMIX	13702	UNS4070
8699409034864	Absorbable Hemostat Oxidized Regenerated Cellulose Knit 15.2 cm x 22.9 cm	OXICEL	35895	OXK13
8699409033812	Neurosurgical Patty - COT 10x75 mm	BETAMIX	13702	CNS1075
8699409032112	Partially Absorbable Composite Mesh 30x30cm	POLYMESH	16048	SCMS030
8699409030149	Surgical Mesh 15x15cm	POLYMESH	16048	PM1515
8699409033072	Adhesion Barrier Gel 10ml	BETAMIX	34212	ABGT10
8699409034840	Absorbable Hemostat Oxidized Regenerated Cellulose Knit 2.6 cm x 2.6 cm	OXICEL	35895	OXK11
8699409034963	Absorbable Hemostat Oxidized Regenerated Cellulose Fibril 10.2 cm x 10.2 cm	OXICEL	35895	OXF16
8699409032105	Partially Absorbable Composite Mesh 20x30cm	POLYMESH	16048	SCM2030
8699409034628	Neurosurgical Patty - PURECOTTON 40x70 mm	BETAMIX	13702	PNS4070
8699409030026	Surgical Mesh 6x11cm	POLYMESH	16048	PM611
8699409033799	Neurosurgical Patty - COT 10x30 mm	BETAMIX	13702	CNS1030
8699409032136	Partially Absorbable Composite Mesh diameter 15cm	POLYMESH	16048	SCMO15
8699409033300	Dual Side Surgical Mesh 20x20cm	POLYMESH	16048	SDM2020
8699409034819	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 15 cm x 23 cm	OXICEL	35895	OXS22
8699409031740	Dual Side Surgical Mesh 7,5x15cm	POLYMESH	16048	SDM715
8699409032143	Partially Absorbable Composite Mesh plug 07cm	POLYMESH	16048	SCMP07
8699409034758	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 5 cm x 35 cm	OXICEL	35895	OXS16
8699409030132	Surgical Mesh 15x10cm	POLYMESH	16048	PM1510
8699409033836	Neurosurgical Patty - COT 12x25 mm	BETAMIX	13702	CNS1225
8699409030095	Surgical Mesh 10x10cm	POLYMESH	16048	PM1010
8699409033133	Partially Absorbable Composite Mesh plug 09cm	POLYMESH	16048	SCMP09
8699409033973	Neurosurgical Patty - COT 70x70 mm	BETAMIX	13702	CNS7070
8699409031726	Dual Side Surgical Mesh 6x14cm	POLYMESH	16048	SDM0614
8699409034048	Neurosurgical Patty - ULTRACOT 12x12 mm	BETAMIX	13702	UNS1212
8699409030651	Adhesion Barrier Gel 5ml	BETAMIX	34212	ABG05
8699409034017	Neurosurgical Patty - ULTRACOT 10x30 mm	BETAMIX	13702	UNS1030
8699409031757	Dual Side Surgical Mesh 8x14cm	POLYMESH	16048	SDM0814
8699409032020	Partially Absorbable Composite Mesh 6x14cm	POLYMESH	16048	SCM0614
8699409033997	Neurosurgical Patty - ULTRACOT 10x10 mm	BETAMIX	13702	UNS1010
8699409030125	Surgical Mesh 9x13cm	POLYMESH	16048	PM913
8699409033843	Neurosurgical Patty - COT 12x40 mm	BETAMIX	13702	CNS1240
8699409030187	Surgical Mesh 15x20cm	POLYMESH	16048	PM1520
8699409033102	Partially Absorbable Composite Mesh 7,5x15cm	POLYMESH	16048	SCM7515
8699409031719	Dual Side Surgical Mesh 6x11cm	POLYMESH	16048	SDM0611
8699409032082	Partially Absorbable Composite Mesh 15x20cm	POLYMESH	16048	SCM1520
8699409030071	Surgical Mesh 7,5x10cm	POLYMESH	16048	PM7510
8699409034765	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 5.1 cm x 7.6 cm	OXICEL	35895	OXS17
8699409034116	Neurosurgical Patty - ULTRACOT 20x70 mm	BETAMIX	13702	UNS2070
8699409031764	Dual Side Surgical Mesh 10x15cm	POLYMESH	16048	SDM1015
8699409034437	Adhesion Barrier Gel 2,5 ml	BETAMIX	34212	ABG205
8699409033829	Neurosurgical Patty - COT 12x12 mm	BETAMIX	13702	CNS1212
8699409031856	Dual Side Surgical Mesh 11cm	POLYMESH	16048	SDMO11
8699409035649	Neurosurgical Patty - SOFT 20x25 mm	BETAMIX	13702	SNS2025
8699409030057	Surgical Mesh 7,5x7,5cm	POLYMESH	16048	PM7575
8699409033348	Dual Side Surgical Mesh 15cm	POLYMESH	16048	SDMO15
8699409034932	Absorbable Hemostat Oxidized Regenerated Cellulose Fibril 15.2 cm x 22.9 cm	OXICEL	35895	OXF13
8699409034161	Neurosurgical Patty - ULTRACOT 40x40 mm	BETAMIX	13702	UNS4040
8699409034888	Absorbable Hemostat Oxidized Regenerated Cellulose Knit 5.1 cm x 10.2 cm	OXICEL	35895	OXK15

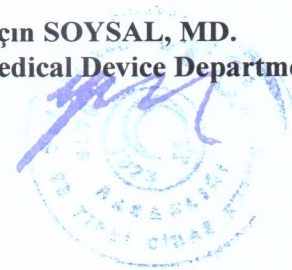
Yalçın SOYSAL, MD.
Head of Medical Device Department

PRODUCT LIST

Barcode	Label Name	Trade Name	GMDN Code	Ref. Number
8699409034208	Neurosurgical Patty - SOFT 5x5 mm	BETAMIX	13702	SNS55
8699409034826	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 12.5 cm x 5 cm	OXICEL	35895	OXS23
8699409033768	Neurosurgical Patty - COT 5x5 mm	BETAMIX	13702	CNS55
8699409030064	Surgical Mesh 7x15cm	POLYMESH	16048	PM715
8699409033416	Dual Side Surgical Mesh 5x8cm	POLYMESH	16048	SDM0508
8699409033294	Dual Side Surgical Mesh plug 11cm	POLYMESH	16048	SDMP11
8699409034604	Neurosurgical Patty - PURECOTTON 40x40 mm	BETAMIX	13702	PNS4040
8699409033966	Neurosurgical Patty - COT 40x70 mm	BETAMIX	13702	CNS4070
8699409033898	Neurosurgical Patty - COT 20x70 mm	BETAMIX	13702	CNS2070
8699409033164	Partially Absorbable Composite Mesh Ventral 6,4x6,4cm	POLYMESH	16048	SCMV2
8699409034291	Neurosurgical Patty - SOFT 12x50 mm	BETAMIX	13702	SNS1250
8699409033911	Neurosurgical Patty - COT 25x25 mm	BETAMIX	13702	CNS2525
8699409034710	Absorbable Hemostat Oxidized Regenerated Cellulose Standard 1.3 x 5.1 cm	OXICEL	35895	OXS12
8699409034055	Neurosurgical Patty - ULTRACOT 12x25 mm	BETAMIX	13702	UNS1225
8699409034550	Neurosurgical Patty - PURECOTTON 20x70 mm	BETAMIX	13702	PNS2070
8699409031870	Dual Side Surgical Mesh plug 07cm	POLYMESH	16048	SDMP07
8699409031900	Dual Side Surgical Mesh R12cm	POLYMESH	16048	SDMR12
8699409032068	Partially Absorbable Composite Mesh 10x15cm	POLYMESH	16048	SCM1015
8699409034475	Neurosurgical Patty - PURECOTTON 10x75 mm	BETAMIX	13702	PNS1075
8699409033041	Adhesion Barrier Gel 2ml	BETAMIX	34212	ABGT02
8699409035663	Neurosurgical Patty - SOFT 25x40 mm	BETAMIX	13702	SNS2540
8699409033959	Neurosurgical Patty - COT 40x50 mm	BETAMIX	13702	CNS4050
8699409033850	Neurosurgical Patty - COT 12x50 mm	BETAMIX	13702	CNS1250
8699409034413	Neurosurgical Patty - SOFT 70x70 mm	BETAMIX	13702	SNS7070
8699409030163	Surgical Mesh 22x35cm	POLYMESH	16048	PM2235
8699409034123	Neurosurgical Patty - ULTRACOT 20x90 mm	BETAMIX	13702	UNS2090
8699409034307	Neurosurgical Patty - SOFT 12x75 mm	BETAMIX	13702	SNS1275
8699409034666	Neurosurgical Patty - PURECOTTON 10x20 mm	BETAMIX	13702	PNS1020
8699409034536	Neurosurgical Patty - PURECOTTON 20x20 mm	BETAMIX	13702	PNS2020
8699409031825	Dual Side Surgical Mesh 26x34cm	POLYMESH	16048	SDM2634
8699409033256	Partially Absorbable Composite Mesh diameter 15cm	POLYMESH	16048	SCMO15
8699409034369	Neurosurgical Patty - SOFT 25x50 mm	BETAMIX	13702	SNS2550
8699409032037	Partially Absorbable Composite Mesh 7x12cm	POLYMESH	16048	SCM0712
8699409031702	Dual Side Surgical Mesh 5x8cm	POLYMESH	16048	SDM0508

End Of Product List
15 February 2017

Yalçın SOYSAL, MD.
Head of Medical Device Department





Certificate of Registration

This is to certify that
Quality Management System
 for Medical Devices
 of

**BETATECH MEDİKAL CİHAZLAR SAN.
 MÜMESSİLLİK İÇ VE DIŞ TİC.LTD. ŞTİ**
 İKİTELLİ ORG. SAN. BLG. ATATÜRK OTO SAN. SİT. ÜNAL İŞ
 MERKEZİ 22. SK. NO: 9, BAŞAKŞEHİR / İSTANBUL / TURKEY.


complies with the requirements of

EN ISO 13485:2012

This certificate is valid concerning all activities related to:

DESIGN, PRODUCTION AND SALES OF STERILE AND NON - STERILE EYE PATCH FOR PHOTOTHERAPY, SURGICAL MESH GROUPS, SURGICAL INCISION COVERS, ADHESION BARRIER FILM AND GELS, BRAIN SURGERY PADS, RESORBABLE HEMOSTAT OXIDIZED REGENERATED CELLULOSE (ORC); REALIZATION OF PRODUCTION AND SALES OF STERILE AND NON - STERILE LIGATION POLYMER CLIPS, TISSUE AND ORGAN BAG AND INCISION RETRACTOR PROTECTIVE PRODUCTS.

STERİL VE NON - STERİL FOTOTERAPİ GÖZ BANTLARI, CERRAHİ MESH GRUPLARI, CERRAHİ İNSİZYON ÖRTÜLERİ, ADEZYON BARIYET FİLM VE JELLERİ, CERRAHİ BEYİN PEDLERİ, EMİLEBİLİR HEMOSTAT OXİDİZED REGENERATED CELLULOSE (ORC) TASARIMI, ÜRETİMİ VE SATIŞI; STERİL VE NON - STERİL POLİMER LİGASYON KLİPSİ, DOKU VE ORGAN TORBASİ VE İNSİZYON KORUYUCU EKARTÖR ÜRÜNLERİNİN ÜRETİMİNİN GERÇEKLEŞTİRİLMESİ VE SATIŞI.

MD-0751 Certificate No.	Oct. 28, 2016 Date of this Certificate	Nov. 25, 2017 *Next Audit Due Date
Nov. 26, 2015 Date of Initial Registration	Nov. 25, 2018 Certification Expiry Date	 Managing Director/Director



TRANSPACIFIC CERTIFICATIONS LIMITED

Website : www.tclcertifications.com E-mail : info@tclcertifications.com
 Accreditation by Joint Accreditation System of Australia and New Zealand (Accreditation No. M2640303IN)
 4 Phipps Close, DEAKIN, ACT 2600, AUSTRALIA
<http://www.jas-anz.org/our-directory/certified-organisations>

This certificate is only valid if it is available/valid on TCL website at <http://tclcertifications.com/client-register/>.

The certificate of Registration remains the property of Transpacific Certifications Limited and shall be returned immediately upon request.
 *In case if Surveillance Audit is not allowed to be conducted on or before the specified date; the Certificate shall be Suspended/Withdrawn.

Gessate, 7 February 2012

CONFORMITY OF GIMA PRODUCTS

According to the annex VII of the Council Directive 93/42/EEC
as amended by the European Directive 2007/47/EEC concerning medical devices

GIMA declares that all medical devices illustrated on

GIMA INTERNATIONAL CATALOGUE

meet the provisions of the following Council Directive (when applicable)

93/42/EEC AS AMENDED BY THE EUROPEAN DIRECTIVE 2007/47/EEC

as below:

- A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).

- B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

GIMA S.p.A.
Q.A. Department
Nicola Manzoni



Reg. Number	10164 - A		
Issuing date	2012-10-15	Last modification date	2015-10-09
Following renewal date	2018-09-14	Settore	EA: 29

Quality Management System Certificate
ISO 9001:2008

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2008 for the following products/services:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer
Giampiero Belcredi



Maintenance of the certification is subject to annual survey and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

This certificate consists of 1 page.

GIMA S.p.A.
Via Marconi, 1
20060 Gessate MI Italia

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Reg. Number 10164 - M
Issuing date 2012-10-15 Last modification date 2015-10-09
Following renewal date 2018-10-14

Quality Management System Certificate
ISO 13485:2003

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2012 for the following products/services:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer
Giampiero Belcredi



Maintenance of the certification is subject to annual survey and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

This certificate consists of 1 page.

GIMA S.p.A.
Via Marconi, 1
20060 Gessate MI Italia

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 02 77608 012

Manufacturer: **Covidien Ilc**
15 Hampshire Street
Mansfield, MA 02048
USA

EC-Representative: **Covidien Ireland Limited**
IDA Business and Technology Park
Tullamore
IRELAND



Product Category(ies): Medical Instruments, Surgical Products and Hemostatic Materials:

- Surgical Suture Products, Pledgets and Retention Tapes
- Endoscopy Instruments and Accessories including Lubricant
- Surgical Staple, Clip Products and Accessories
- Manual Surgical Instruments
- Implantable Wound Dressing Materials
- Ultrasonic Surgical Devices and Accessories
- Suction / Irrigation Devices and Accessories
- Arthroscopy Implants, Instruments and Accessories
- Bone Wax
- Temporary Cardiac Pacing Lead

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713078138

Valid from: 2016-04-17

Valid until: 2021-04-16

Date, 2016-04-05

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 02 77608 012

Facility(ies):

Covidien (U.S.S.C. Puerto Rico, Inc.)
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731,
USA

Covidien (Davis & Geck Caribe, Ltd.)
Zona Franca de San Isidro, Carretera San Isidro Km 17, Santo
Domingo, DOMINICAN REPUBLIC

Covidien
Boulevard Insurgentes, 19030 Libramiento, 22225 Tijuana, B.C.,
MEXICO

Covidien Deutschland Manufacturing GmbH
Gewerbepark 1, 93333 Neustadt/ Donau, GERMANY

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

Covidien Medical Products (Shanghai) Manufacturing L.L.C.
Building#10,789 Puxing Road, 201114 Shanghai, PEOPLE'S
REPUBLIC OF CHINA

CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016 ISO 9001:2015

Scope:

Sales, order management, warehousing and distribution of medical devices.
Including inventory management, regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2021
Certificate effective date: 1 July 2018
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:

	Different scope
Medtronic Portugal LDA- Rua Tomas da Fonseca Torre E, 11 piso 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices including technical service and customer education. Warehousing and distribution of medical devices, including spine loaner operations
Medtronic Italia S.p.A. Via Varesina 162 20156 Milano Italy	Sales, order management and distribution of medical devices. Including technical service and customer education. Promotion, invoice and order management of medicinal products.
Medtronic Danmark A/S. Arne Jacobsens Allé 17 2300 Kopenhagen Denmark	Sales, order management and distribution of medical devices. Including technical service and customer education
Medtronic Medikal Teknoloji Ticaret Ltd Sti Saray Mah. Esnaf Sk. Akkom Ofis Park Laodik Plaza Sitesi B Blok Apt: 2/8 00000 Umraniye - Istanbul Turkey	Sales, order management and distribution of medical devices. Including technical service and customer education

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd.
Waterfall Distribution Campus
CNR K101 and Bridal Veil Road
Waterfall Midrand
1685 Gauteng
South Africa

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Ibérica S.A.
Calle de María de Portugal, 11
28050 Madrid
Spain

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Romania SRL
Ploiesti 42-44, Building B, B2
Wing, 2nd floor, district 1
Baneasa Business & Technology Park
013696 Bucharest
Romania

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Norge AS
Martin Linges vei 25
1364 Fornebu
Norway

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Portugal, LDA-
Avenida Gomes Pereira 61B
Benfica
1600 Lisboa
Portugal

Sales, Order Management and distribution of medical devices Including technical service and customer education.

Warehousing and distribution of medical devices, including spine loaner operations.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Service & Repair CoE
C-Mill gebouw K
Jan Campertstraat 21-A
6416 SG Heerlen

Service and repair of medical devices (excluding Imaging and Navigation products).

Medtronic Ibérica S.A.
Polígono Industrial La Garena
Calle Francisco Rabal 7
28806 Alcalá De Heneras, Madrid
Spain

Spine loaner operations.

Medtronic Ibérica S.A.
WTC Almeda Park
Placa de la Pau, s/n. Edificio 7, 3 piso
08940 Cornellà de Llobregat, Barcelona
Spain

Warehousing and distribution of medical devices, including spine loaner operations

Medtronic France SAS
27/33 Quai Alphonse Le Gallo
92513 Boulogne-Billancourt
France

Sales, order management and distribution of medical devices. Including technical Service and customer education

Medtronic Trading NL B.V.
Larixplein 4
5616 VB Eindhoven

Sales, order management and distribution of medical devices. Including technical service and customer education

Medtronic GmbH
Earl-Bakken-Platz 1
40670 Meerbusch
Germany

Distribution of medical Devices, medical equipment and related services.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Osterreich GmbH
Millennium Tower, 20th floor
Handelskai 94-96
1200 Wien
Austria

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic (Schweiz) AG
Talstrasse 9
3053 Munchenbuchsee
Switzerland

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic Hellas S.A.
Avenue Kifisias 24 Building B
151 25 Marousi Pref. Attica
Greece

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Serbia Ltd.
Bulevar Zorana Djindjica, 64a
11070 Belgrade
Serbia

Sales, order management and distribution of medical devices.

Medtronic Hungária Kft.
Bocskai út 134-146
Cépulet 3. emelet
1113 Budapest
Hungary

Sales, order management and distribution of medical devices. Including customer education.

Medtronic CCO SSC Warsaw
Polna 11
00-633 Warszawa
Poland

Order management of medical devices.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Finland Oy
Lentäjätie 3
01530 Vantaa
Finland

Sales, order management and distribution of medical devices.
Including technical service and customer education.

Medtronic AB
P.O. Box 1034
164 21 Kista
Sweden

Sales, order management and distribution of medical devices.
Including technical service and customer education

Medtronic Trading Ltd.
10 Hamada Street
4673344 Herzlyia
Israel

Import, sales, order management and distribution of medical
devices. Including technical service and customer education

Addendum expiry date: 1 July 2021
Addendum effective date: 1 July 2018

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, production and distribution
of disposable and reusable medical devices for surgical and
patient care procedures. Servicing of suction devices.
(see attachment for site included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-06-29
Certificate Registration No.: SX 60130220 0001
An audit was performed. Report No.: 26300270 007
This Certificate is valid until: 2021-04-13

Certification Body



Date 2018-06-29

Maciej Sciera
Maciej Sciera



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60130220 0001
Report No.: 26300270 007

Organization: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

Scope:

Site included:

Grena Ltd.
Chelsea House
Chelsea Street
Nottingham NG7 7HP
United Kingdom

Activity: Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures. Especially: production, purchasing, logistics and distribution of disposable and reusable medical devices.

Certification Body



Date: 2018-06-29

Maciej Sciera



ORDIN DE PLATA NR.: 44

TIP.DOC. 1 :

DATA EMITERII:14 februarie 2019 :

PLATITI: 3600-00 LEI: Trei Mii Sase Sute lei 00 bani :

PLATITOR: (R) "BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L. MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :

PRESTATORUL PLATITOR CODUL BANCII :
BC"Moldindconbank"S.A. suc."Invest" Chisinau :MOLDM2X329:

BENEFICIAR (R) Institutul CONTUL DE PLATI/CODUL IBAN :
de Medicina Urgenta IMSP MD55VI022510300000002MDL :
CODUL FISCAL :1003600152606 / :

PRESTATORUL BENEFICIAR CODUL BANCII :
B.C."VICTORIABANK"S.A. :VICBMD2X :

DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la licitatie publica nr. ocds-b: NORMAL/URGENT :N:
3wdp1-MD-1547119757989 din 15.02.2019

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:14/02/2019

DATA EXECUTARII:

: SEMNATURILE

: EMITENTULUI

CONducator:Web "BIOSISTEM MLD" SRL Director :
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SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

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(semnatura electronica)

CONTABIL-SEF:Web "BIOSISTEM MLD" SRLContabil :
MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
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DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowgY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKEx5NZWR1Y29yIFN0cWwmlvc2lzdGVTIE1MRCBTUkwxEjAQBGNVBAsT :

L.S. (semnatura electronica)

CONducator: (semnatura manuala)

CONTABIL-SEF: (semnatura manuala)

SEMnatura PRESTATORUL L.S.

MOTIVUL REFUZULUI : L.S.