Digitally signed by Poiata Vitalie
Date: 2019.02.06 12:49:03 EET
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

L.Ș.

Notă: Licența este valabilă numai cu anexa autentificată 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. Московей, 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 MD95ML0000000002251429243**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

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

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

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 **Lazari Aliona**
tel. 022-266-252

A A 7 * E A * 0 3 7 0 4 3 1 E A

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

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

Data primirii 27.03.2018 13:54:13

Anexe la SNC
"Prezentarea situaţiilor financiare"
Aprobat de Ministerul Finanţelor al Republicii Moldova

SITUAŢIILE 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 (Cod poştal) MUN.CHIŞINĂU; MUN.CHIŞINĂU SEC.RÎŞCANI
Raionul (municipiul, UTA); Localitatea
Albisoara, 16, 1, of.7
strada, nr, bl.

150 Cod CUATM

Activitatea principală: Comert cu ridicata al produselor farmaceutice

G4646 Cod CAEM, rev.2

Forma de proprietate: Proprietate privată

15 Cod CFP

Forma organizatorico-juridică: SOCIETATI CU RASPUNDERE LIMITATA

530 Cod CFOJ

Date de contact: Tel. +37322808719 e-mail biosistem.mld@gmail.com
WEB:

Numele şi coordonatele al contabilului-şef: Dl (dna) +37322808719
Tel. +37369463619

Unitatea de măsură: leu

Anexa 8

Notă informativă privind veniturile şi cheltuielile clasificate după natură

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vînzări	010	15.623.709	20.497.176
Alte venituri din activitatea operaţională	020		500
Venituri din alte activităţi	030	368.943	361.872
Total venituri (rd.010 + rd.020 + rd.030)	040	15.992.652	20.859.548
Variaţia stocurilor	050		
Costul vînzărilor	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
Contribuţii de asigurări sociale de stat obligatorii şi prime de asigurare obligatorie de asistenţă medicală	090	35.709	46.530
Cheltuieli cu amortizarea şi deprecierea activelor imobilizate	100	7.389	90.494
Alte cheltuieli	110	306.855	548.183
Cheltuieli din alte activităţi	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

Anexa 1

BILANŢUL

la 31.12.2017

Nr. crt.	ACTIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrşitul perioadei de gestiune
1	2	3	4	5
1.	**Active imobilizate**			
	Imobilizări necorporale	010	2.437	1.787
	Imobilizări corporale în curs de execuţie	020		
	Terenuri	030		
	Mijloace fixe	040	195.525	904.703
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investiţii financiare pe termen lung în părţi neafiliate	070		
	Investiţii financiare pe termen lung în părţi afiliate	080		
	Investiţii imobiliare	090		
	Creanţe 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**			
	Materiale	140	2.329	457
	Active biologice circulante	150		
	Obiecte de mică valoare şi scurtă durată	160	49.454	63.968
	Producţia în curs de execuţie şi produse	170		
	Mărfuri	180	3.435.875	4.430.031
	Creanţe comerciale	190	5.303.786	3.157.174
	Creanţe ale părţilor afiliate	200		
	Avansuri acordate curente	210	793.582	1.097.547
	Creanţe ale bugetului	220	35.037	4.973
	Creanţe ale personalului	230		
	Alte creanţe curente	240		
	Numerar în casierie şi la conturi curente	250	747.829	4.742.040
	Alte elemente de numerar	260		
	Investiţii financiare curente în părţi neafiliate	270		
	Investiţii financiare curente în părţi 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	Sfîrşitul perioadei de gestiune
1	2	3	4	5
3.	**Capital propriu**			
	Capital social şi suplimentar	320	5.400	5.400
	Rezerve	330		
	Corecţii ale rezultatelor anilor precedenţi	340	X	
	Profit nerepartizat (pierdere neacoperită) al anilor precedenţi	350	8.952.137	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	360	X	6.996.028
	Profit utilizat al perioadei de gestiune	370	X	
	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 faţă de părţile afiliate	480		
	Avansuri primite curente	490	186.214	7.303
	Datorii faţă de personal	500	7.343	45.149
	Datorii privind asigurările sociale şi medicale	510		
	Datorii faţă de buget	520	318.484	39.698
	Venituri anticipate curente	530		
	Datorii faţă de proprietari	540		
	Finanţări şi încasări cu destinaţie 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

Anexa 2

SITUAŢIA DE PROFIT ŞI PIERDERE

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vînzări	010	15.623.709	20.497.176
Costul vînzărilor	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 operaţională	040		500
Cheltuieli de distribuire	050	208	202
Cheltuieli administrative	060	513.937	522.704
Alte cheltuieli din activitatea operaţională	070	272.514	350.476
Rezultatul din activitatea operaţională: profit (pier-dere) (rd.030 + rd.040 – rd.050 – rd.060 – rd.070)	080	4.876.829	8.152.126
Rezultatul din alte activităţi: profit (pierdere)	090	79.511	-196.904
Profit (pierdere) pînă la impoztare (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

Anexa 3

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2017 pînă la 31.12.2017

Nr. d/o	Indicatori	Cod rd.	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrşitul perioadei de gestiune
1	2	3	4	5	6	7
1	**Capital social şi suplimentar**					
	Capital social	010	5.400			5.400
	Capital suplimentar	020				
	Capital nevărsat	030	0	0	0	0
	Capital neînregistrat	040				
	Capital retras	050	0	0	0	0
	Total capital social şi 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 reserve (rd.070 + rd.080 + rd.090)	100				
3	**Profit nerepartizat (pierdere neacoperită)**					
	Corecţii ale rezultatelor anilor precedenţi	110				
	Profit nerepartizat (pierdere neacoperită) al anilor precedenţi	120	8.952.137	4.361.103	7.669.613	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	130	X	6.996.028		6.996.028
	Profit utilizat al perioadei de gestiune	140	X	0	0	0
	Rezultatul din tranziţia 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	7.669.613	12.639.655
4	**Alte elemente de capital propriu, din care**	170				
	Diferenţe din reevaluare	171				
	Subvenţii entităţilor cu proprietate publică	172				
	Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180	8.957.537	11.357.131	7.669.613	12.645.055

Anexa 4

SITUAŢIA FLUXURILOR DE NUMERAR

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 operaţională			
Încasări din vînzări	010	16.364.220	30.547.593
Plăţi pentru stocuri şi servicii procurate	020	18.057.882	1.242.716
Plăţi către angajaţi şi organe de asigurare socială şi medicală	030	165.559	205.235
Dobînzi plătite	040		
Plata impozitului pe venit	050	359.402	1.213.720
Alte încasări	060	2.173.630	
Alte plăţi	070	647.102	20.861.222
Fluxul net de numerar din activitatea operaţională (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 investiţii			
Încasări din vînzarea activelor imobilizate	090		
Plăţi aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
Alte încasări (plăţi)	130		
Fluxul net de numerar din activitatea de investiţii (rd.090 – rd.100 + rd.110 + rd.120 + rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite şi împrumuturi	150		
Plăţi aferente rambursării creditelor şi împrumuturilor	160		
Dividende plătite	170	1.127.660	3.110.000
Încasări din operaţiuni de capital	180		
Alte încasări (plăţi)	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
Diferenţe 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 sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	747.829	4.742.040

Anexa 6

Date generale

1. Certificat de înregistrare a entităţii, 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 deţinătorilor a cel puţin 20% ——— lei,
Modificări ulterioare:
a) ———, suma ——— lei, inclusiv cota statului ——— lei,
b) ———, suma ——— lei, inclusiv cota statului ——— lei,
3. Entităţile, activitatea cărora necesită licenţă, indică:
Licenţa 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 licenţa ———
4. Numărul mediu scriptic al personalului în perioada de gestiune 3 persoane, inclusiv pe categorii:
1) personal administrativ 3 persoane,
2) muncitori ——— persoane,
5. Numărul personalului la 31.12.2017 3 persoane.
6. Remunerarea personalului entităţii în perioada de gestiune 169.200 lei.
7. Remunerarea membrilor organelor de administrare, de conducere şi supraveghere şi alte angajamente apărute sau asumate în legătură cu pensiile membrilor actuali sau ale foştilor membri ai acestor organe, pe categorii ——— lei
8. Avansurile şi creditele acordate membrilor organelor specificate la pct.7 ——— lei, inclusiv rambursate ——— lei.
9. Valoarea activelor imobilizate şi circulante, înregistrate în calitate de gaj[1]
1) valoarea de gaj ——— lei,
2) valoarea contabilă ——— lei.
10. Numărul acţiunilor ordinare la finele perioadei de gestiune ——— unităţi.
11. Profit net (pierdere netă) a perioadei de gestiune pentru o acţiune ordinară:
1) profit ——— lei,
2) pierdere ——— lei.
12. Dividende calculate pentru o acţiune ordinară pentru perioada de gestiune:
1) plătite ——— lei,
2) planificate pentru plată ——— lei.
13. Valută străină disponibilă, recalculată în monedă naţională a Republicii Moldova – total 849.462 lei, inclusiv (lei, denumirea şi 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 fracţie se reflectă:
a) la numărător – valoarea de gaj;
b) la numitor – valoarea contabilă

———

Anexa 7

Informatiile privind activele imobilizate

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Nr. rînd	Existenţa 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)	Ieşirea în cursul perioadei (la costul de intrare)	Existenţa la sfîrşitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrşitul perioadei	Deprecierea acumulată la sfîrşitul perioadei
1		2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuţie	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200	3.250	813				3.250	1.463	
2.1 brevete şi mărci	210								
2.2. licenţe de activitate	220	3.250	813				3.250	1.463	
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuţie	300								
4. Terenuri	400		X					X	
5. Mijloace fixe, total din care:	**500**	**205.204**	**9.679**		**796.422**	**6.100**	**995.526**	**90.823**	
5.1. clădiri	510								
5.2. construcţii speciale	520								
5.3. maşini, utilaje, instalaţii de transmisie	530	186.815	8.300		796.422	6.100	977.141	85.929	
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente şi inventar	550								
5.6. cesturi ulterioare aferente obiectelor neînregistrate în bilanţ	560								
5.7. mijloace fixe primite în leasing financiar	570								
5.8. mijloace fixe primite în gestiune economică	580								
5.9. alte mijloace fixe	590	18.385	1.379				18.385	6.894	
6. Resurse minerale	**600**								
7. Investiţii 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 organizaţiei	40717392
Codul fiscal al organizaţiei	1010600028048
IDNO organizaţiei	1010600028048
Denumirea organizaţiei	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. Chişinău
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.

Anexa nr.7 la Instrucțiunea aprobată prin ordinul IFPS nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A1902990 **din** / от 24.01.2019

1. Destinatar / Получатель

Pentru participarea la proceduri de achizitii 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 08.02.2019

5. Autentificarea organului fiscal / Подтверждение налогового органа

Sef DAF Riscani — Semnătura/Подпись — Ana Stoicov

Funcția/Должность — **Semnătura**/Подпись — **Numele și prenumele**/Фамилия и имя

L.Ș/ М.П.

Executor: _____
Numele și prenumele/Фамилия и имя

MINISTERUL FINANȚELOR AL REPUBLICII MOLDOVA · SERVICIUL FISCAL DE STAT · IDNO 1006601001182 · S7

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 24.01.2019 ora 8:54:20 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,89)

ORDIN DE PLATA NR.: 37 TIP.DOC. 1

DATA EMITERII:5 februarie 2019

PLATITI: 500-00 LEI: Cinci Sute lei 00 bani

PLATITOR: (R) 'BIOSISTEM MLD" SRL
CONTUL DE PLATI/CODUL IBAN
MD95ML0000000022514292 43
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau
CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R)INSTITUTUL D E NEUROLOGIE SI NEUROCHIRURGI E
CONTUL DE PLATI/CODUL IBAN
MD52VI022511700000034MDL
CODUL FISCAL :1003600150602 /

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

DESTINATIA PLATII:"Pentru garantia pentr: u oferta la licitatia publica nr. ocds-b3wdp1-MD-1547727761237 din 07.02.2019

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:05/02/2019
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web "BIOSISTEM MLD" SRL Director

MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBEowggRGMIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTEQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxFzA

(semnatura electronica)

CONTABIL-SEF:Web "BIOSISTEM MLD" SRLContabil

MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowgY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKEx5NZWRlY29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAsT

L.S. (semnatura electronica)

CONDUCATOR: _____
(semnatura manuala)

CONTABIL-SEF: _____
(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

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

Company Name	: Betatech Medikal Cihazlar Sanayi Mümessillik İç ve Dış Tic. Ltd. Şti.
Company Address	: İki Telli Organize Sanayi Bölgesi Atatürk Oto Sanayi Sitesi, 22 Sok. Ünal İş Merkezi No:9 Başakşehir ISTANBUL / 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

Addres: 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 expiresafter 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

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	BETAMİX	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	BETAMİX	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 11cm	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 6x11cm	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	SCM3030
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

TRANSPACIFIC CERTIFICATIONS LIMITED

AMENDED DUE TO CHANGE IN ADDRESS

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 BARİYET 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 TORBASI VE İNSİZYON KORUYUCU EKARTÖR ÜRÜNLERİNİN ÜRETİMİNİN GERÇEKLEŞTİRİLMESİ VE SATIŞI.

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

JAS-ANZ

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.

Version 1.00

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) – Italy
www.gimaitaly.com

EXPORT DIVISION
tel. +39 02 953854209/221/225
fax +39 02 95380056
export@gimaitaly.com

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

Certificate

kiwa
Partner for progress

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

CERMET

IAF INTERNATIONAL ACCREDITATION FORUM

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 007A SSI N° 006G
SGA N° 010D FSM N° 004I
PRD N° 069B

Certificate

kiwa
Partner for progress

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

CERMET

IAF INTERNATIONAL ACCREDITATION FORUM

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 007A SSI N° 006G
SGA N° 010D FSM N° 004I
PRD N° 069B

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60100980 0001

Report No.: 26300270 002

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

Products: (see attachments for products and site included)

Replaces approval, registration no.: DD 60040589 0001

Expiry Date: 2020-04-13

The Notified Body hereby declares that the requirements of Annex V 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, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2015-04-30

Date: 2015-04-30

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60100980 0001
Report No.: 26300270 002

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

Products included:

- Disposable trocars
- Infusion sets
- Retrieval bags
- Disposable skin staplers
- Suction cannulas and suction sets
- Thoracentesis/Paracentesis sets
- Transfusion sets
- Veress needles
- Thoracic catheters
- Suction-irrigation sets
- Silicone slings

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Disposable skin staples removers
- Chest drainage systems
- Connecting tubes
- Absorbing pads

Date: 2015-04-30

TÜV Rheinland LGA Products GmbH

Notified Body

Dipl.-Ing. S. Pane

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60100980 0001
Report No.: 26300270 002

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

Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

TÜV Rheinland LGA Products GmbH

Notified Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60100981 0001

Report No.: 26300270 002

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

Products: (see attachments for products and site included)

Replaces approval, registration no.: HD 60040590 0001

Expiry Date: 2020-04-13

The Notified Body 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, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2015-04-30

Date: 2015-04-30

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60100981 0001
Report No.: 26300270 002

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

Products included:

- Reusable endoscopic surgical instruments
- Disposable endoscopic surgical instruments
- Disposable linear cutting staplers with cartridges
- Disposable linear staplers with cartridges
- Disposable circular staplers with related surgical instruments
- Staples cartridges for reusable circular staplers
- Staples cartridges for reusable linear staplers
- Ligating clips
- Surgical meshes
- Cartridges for disposable endoscopic linear cutting staplers
- Disposable endoscopic linear cutting staplers

Notified Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60100981 0001
Report No.: 26300270 002

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

Site included:

Grena Limited
Chelsea House,Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Notified Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

TÜVRheinland®

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
(See attachment for site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date:	2015-04-30
Certificate Registration No.:	SX 60100982 0001
An audit was performed. Report No.:	26300270 002
This Certificate is valid until:	2018-04-13

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH

Date 2015-04-30

Dipl.-Ing. S. Pane

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60100982 0001
Report No.: 26300270 002

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

Scope:

Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Distribution

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland

Date: 2015-04-30

Dipl.-Ing. S. Pane

TÜVRheinland®

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 the following scope:

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

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

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

Effective Date:	2015-04-30
Certificate Registration No.:	SY 60100983 0001
An audit was performed. Report No.:	26300270 002
This Certificate is valid until:	2018-04-13

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland

Dipl.-Ing. S. Pane

Date 2015-04-30

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

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SY 60100983 0001
Report No.: 26300270 002

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

Scope:

Site included:

Grena Limited
Chelsea House, Chelsea Street,
Nottingham, NG7 7HP,
United Kingdom

Distribution

Certification Body

Date: 2015-04-30

Dipl.-Ing. S. Pane

GRENA®

VAT no. GB 821 2900 64

1000 Great West Road, Brentford, Middlesex TW8 9HH,.UK Phone +44 131 208 207 6 Fax +44 131 777 80 77

DECLARATION OF CONFORMITY

Manufacturer

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

Product(s)

Disposable circular staplers with related surgical instruments (class IIb, rule 8)
Disposable linear staplers and cartridges for linear staplers (class IIb, rule 8)
Disposable bone marrow aspiration needles (class IIa, rule 6)
Disposable bone marrow biopsy needles (class IIa, rule 6)
Disposable staples cartridges for reusable linear staplers (class IIb, rule 8)
Disposable staples cartridges for reusable circular staplers (class IIb, rule 8)
Disposable endoscopic linear cutting staplers (class IIa, rule 6)
Cartridges for disposable endoscopic linear cutting staplers (class IIb, rule 8)
Surgical meshes (class IIb, rule 8)
Disposable automatic clip appliers with clips (class IIb, rule 8)
LigaV® – Titanium ligating clips (class IIb, rule 8)
VClip® – Titanium ligating clips (class IIb, rule 8)
Click'a-V® – Polymer ligating clips (class IIb, rule 8)
Disposable endoscopic instruments:
- Disposable grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
- Disposable grasper with ratchet-Allis (class IIb, rule 9)
- Disposable grasper with ratchet-Maxi Grip (class IIb, rule 9)
- Disposable toothed grasper with ratchet (class IIb, rule 9)
- Disposable grasper with ratchet –Babcock (class IIb, rule 9)
- Disposable Metzenbaum scissors-curved (class IIb, rule 9)
- Disposable scissors-straight (class IIb, rule 9)
- Disposable scissors-hook (class IIb, rule 9)
- Disposable dissector-Maryland (class IIb, rule 9)
- Disposable dissector with ratchet- Maryland (class IIb, rule 9)
- Disposable endoscopic dissector 3mm – Maryland, non-ratcheted
- Disposable endoscopic dissector 3mm – Maryland, ratcheted
- Disposable endoscopic grasper 3mm – atraumatic fenestrated
- Disposable endoscopic scissors 3mm – curved

Limited use endoscopic instruments:
- Limited use dissector- Maryland (class IIb, rule 9)
- Limited use dissector with ratchet- Maryland (class IIb, rule 9)
- Limited use Metzenbaum scissors- curved (class IIb, rule 9)
- Limited use scissors-straight (class IIb, rule 9)
- Limited use scissors-hook (class IIb, rule 9)
- Limited use grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
- Limited use disposable grasper with ratchet-Allis (class IIb, rule 9)
- Limited use grasper with ratchet-Maxi Grip (class IIb, rule 9)
- Limited use toothed grasper with ratchet (class IIb, rule 9)
- Limited use grasper with ratchet –Babcock (class IIb, rule 9)

Reusable endoscopic surgical instruments (class IIb, rule 9)
Disposable linear cutting staplers and cartridges for cutting staplers (class IIb, rule 8)
Disposable trocars with accessories (class IIa, rule 7)
Sterile disposable skin staplers (class IIa, rule 7)
Thoracentesis/paracentesis sets (class IIa, rule 6)
Suction cannulas and suction sets (class IIa, rule 7)
Suction-irrigation sets (class IIa, rule 6)
Disposable skin staples removers (class I sterile, rule 1)
Chest drainage systems (class I sterile, rule 1)
Connecting tubes (class I sterile, rule 1)
Retrieval bags (class IIa, rule 6)
Veress needles (class IIa, rule 6)
Silicone slings (class IIa, rule 6)
Arida® absorbing pads (class I, rule 1)
Arida® absorbing pads – sterile (class I sterile, rule 1)
Solidifying agent (class I, rule 1)
Open surgery and endoscopic clip appliers (class I, rule 6)
Vomit bags (class I, rule 1)

Grena Limited – Incorporated in England & Wales – Company No. 04793131

GRENA®

VAT no. GB 821 2900 64

1000 Great West Road, Brentford, Middlesex TW8 9HH,.UK Phone +44 131 208 207 6 Fax +44 131 777 80 77

Classification According to Annex IX of Directive 93/42/EEC

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the directive 93/42/EEC concerning medical devices which apply to them. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied

All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.

Notified Body

CE 0197

TÜV Rheinland LGA Products GmbH
Lillystrasse 2
90431 Nürnberg
Germany

EC Certificate(s)

HD 60040590 0001
DD 60040589 0001

Brentford, 09.05.2014

Wiesław Brodaczewski
Director

Grena Limited – Incorporated in England & Wales – Company No. 04793131

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-06-29

Sciera Maciej

Maciej Sciera

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2018-06-29

Sciera

Maciej Sciera

GRENA

GRENA 25 YEARS committed to healthcare

Vomit Bag

Safe and hygienic protection

- Extra low volume scale
- Twist and seal lock
- Pre-gelled version
- Hard plastic rim

GRENA

proud to be a member of
LONDON CHAMBER of COMMERCE AND INDUSTRY

Vomit Bag

Vomit Bag

Key features

Ergonomically designed for the safe and hygienic collection of vomit in stationary use and on the move.

Easy to hold and simple to dispose of, the Vomit Bag surpasses the kidney dish for safety and functionality minimizing the chance of cross infection, as well as eliminating clothes and bed linen contamination.

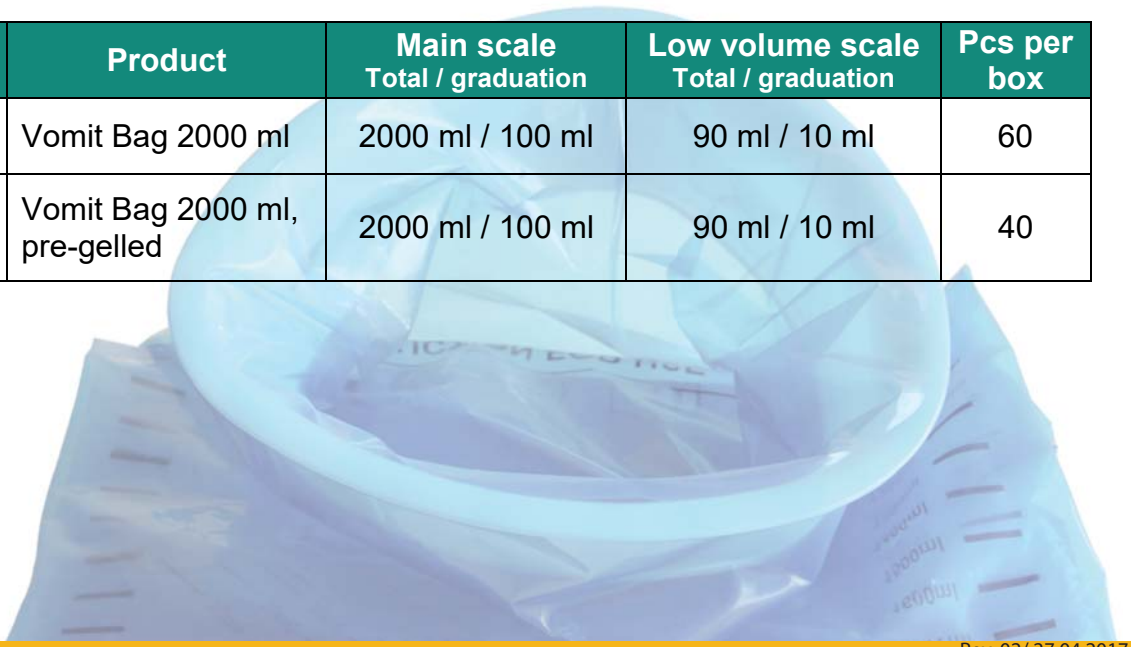
With an easy to hold hard plastic rim that fits perfectly over the patients' mouths, the Vomit Bag completely holds vomit.

The Vomit Bag protects staff and patients, and reduce cleaning costs. Product is latex free.

The Vomit Bag features volume markings with an extra low volume scale to allow precise monitoring of fluid loss. The twist and seal lock traps odour and content.

The pre-gelled version solidifies and encapsulates fluids eliminating the need to transport biohazardous vomits in liquid form and minimizing the possibility of spreading them on the surfaces. It also reduces unpleasant odour.

REF	Product	Main scale Total / graduation	Low volume scale Total / graduation	Pcs per box
0507-VB2000	Vomit Bag 2000 ml	2000 ml / 100 ml	90 ml / 10 ml	60
0507-VB2000PG	Vomit Bag 2000 ml, pre-gelled	2000 ml / 100 ml	90 ml / 10 ml	40



Rev. 02/ 27.04.2017

Grena Ltd.
1000 Great West Road, Brentford, Middlesex, TW8 9HH, UK
www.grena.co.uk

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 llc
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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

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

MGMT. SYS.
RvA C 589

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 Milennium 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 Cépület 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 Lentäjäntie 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 Herzlya 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