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ORDIN DE PLATA NR.: 665                                TIP.DOC. 1 :
                                DATA EMITERII:25 martie 2021 :
=====:
PLATITI: 1000-00                                LEI: Una Mie 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                                :MOLDMD2X329:
=====:
BENEFICIAR (R) IMSP Spital                                CONTUL DE PLATI/CODUL IBAN :
ul Clinic Municipal Balti                                MD77ML000000002251821544 :
                                CODUL FISCAL :1003602150732 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
BC"Moldindconbank"S.A.                                :MOLDMD2X :
=====:
DESTINATIA PLATII:Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizi?ie public: NORMAL/URGENT :N:
a nr. ocde-b3wdpl-MD-1614340230185 din 3: :
1.03.2021 : :
: :
: L.S. :
=====:
                                CODUL TRANZACTIEI:001: :
DATA PRIMIRII:25/03/2021 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONDUCTOR:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIIGVDCBBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:
DQEHAAACCBGawggRoMIIDUKADAgECAhNHAACjbilrgFksQ0G4AAAAAKNuMA0GCSq:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQml :
-----:
                                (semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIIGVDCBBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:
DQEHAAACCBHawggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkwOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
-----:
L.S.                                (semnatura electronica) :
CONDUCTOR:                                :
                                (semnatura manuala) :
CONTABIL-SEF:                                :
                                (semnatura manuala) :
SEMNATURA PRESTATORUL                                L.S. :
:-----:
MOTIVUL REFUZULUI                                : L.S. :
-----:

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BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, 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



BIOSISTEM-MLD S.R.L.

Cod Fiscal: 1010600028048; IBAN: MD95ML000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poștală a băncii: mun. Chișinău, bd. Moscovei, 14/1;

Scrisoare de informare

Prin prezenta, SRL „Biosistem mld”, va informeaza ca conform “*legii Nr. 160 din 22-07-2011 privind reglementarea prin autorizare a activității de întreprinzător*”, cu modificarile ulterior adoptate de parlamentul RM, *Importul, comercializarea, asistența tehnică si reparația dispozitivelor medicale* nu mai este activitate licentiata. Respectiv nu mai sunt eliberate licente pentru acest gen de activitate, iar licentele cu termenul de valabilitate expirat nu mai sunt prelungite.

_____ Vitalie Poiata

L.Ș.

Data prezentării 21.05.2020 10:13:29
SITUATIILE FINANCIARE

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

2019 pentru perioada 01.01.2018 - 31.12.2019 de lichidare

BIROUL NAȚIONAL DE STATISTICA

Entitate: BUSISTEM MLD S.R.L.
Sediu: SEC. RISCANI, STR. ALBISOARA NR.16 BL.1 OF.7
Raionul(municipiul): 106, DDF RISCANI
Satul(communa):
Strada: SEC. RISCANI, STR. ALBISOARA NR.16 BL.1 OF.7
Cod postal: 2001
Cod CUATM: 2150, SEC. RISCANI
Activitatea principala: 6464, Comerț cu ridicata al produselor farmaceutice
Forma proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată
Cod CUIO: 40711790
Codul fiscal: 1010500028048
WEB:
Numele și coordonatele al contabilului-sef: Nasedchin Alexandr
Telefon: +37322808719
Numărul mediu scrisor al personalului in perioada precedenta: g persoane.

Unitatea de masura: leu

Notă informativă privind veniturile și cheltuielile clasificate după natură

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	010		
Alte venituri din activitatea operationala	020		
Venituri din alte activitati	030		
Total venituri (rd.010 + rd.020 + rd.030)	040		
Variatia stocurilor	050		
Costul vinzarilor mărfurilor vândute	060		
Cheltuieli privind stocurile	070		
Cheltuieli cu personalul privind remunerarea muncii	080		
Contributi de asigurari sociale de stat obligatorii si prime de asigurare obligatorie de asistenta medicala	090		
Cheltuieli cu amortizarea si deprecierea activelor imobilizate	100		
Alte cheltuieli	110		
Cheltuieli din alte activitati	120		
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130		
Profit (pierdere) pina la impozitare (rd.040 - rd.130)	140		
Cheltuieli privind impozitul pe venit	150		
Profit (pierdere) net al perioadei de gestiune (rd.140 - rd.150)	160		

BILANȚUL

la

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
1.	Active imobilizate			
	Imobilizari necorporale	010	1137	487
	Imobilizari corporale in curs de executie	020		
	Terenuri	030		
	Mijloace fixe	040	938614	2208593
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investitii financiare pe termen lung in parti neafiliate	070		
	Investitii financiare pe termen lung in parti afiliate	080		
	Investitii imobiliare	090		
	Creante 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	939751	2209080
	Active circulante			
	Materiale	140		6209

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
2.	Active biologice circulante	150		
	Obiecte de mica valoare si scurta durata	160	51520	47842
	Productia in curs de executie si produse	170		
	Mărfuri	180	4809995	5710647
	Creante comerciale	190	5528804	4327728
	Creante ale partilor afiliate	200		
	Avansuri acordate curente	210	2496545	1647170
	Creante ale bugetului	220	26401	166486
	Creante ale personalului	230		
	Alte creante curente	240		
	Numerar in casierie si la conturi curente	250	9066228	8911899
	Alte elemente de numerar	260		
	Investitii financiare curente in parti neafiliate	270		
	Investitii financiare curente in parti afiliate	280		
	Alte active circulante	290	3712	742
	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	21983205	20828724
	Total active (rd.130 + rd.300)	310	22922956	23037804
3.	Capital propriu			
	Capital social si suplimentar	320	5400	5400
	Rezerve	330		
	Corectii ale rezultatelor anilor precedenti	340	x	
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	350	18182879	12119049
	Profit net (pierdere neta) al perioadei de gestiune	360		8902436
	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	18188279	21026865
	Datorii pe termen lung			
	Credite bancare pe termen lung	400		
	Imprumuturi 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		
	Datorii curente			
	Credite bancare pe termen scurt	450		
	Imprumuturi pe termen scurt	460		
	Datorii comerciale	470	3883519	1331928
4.	Datorii fata de partile afiliate	480		
	Avansuri primite curente	490	135390	159545
	Datorii fata de personal	500	152404	2913
	Datorii privind asigurarile sociale si medicale	510		
	Datorii fata de buget	520	492060	434590
	Venituri anticipate curente	530		
	Datorii fata de proprietari	540		
	Finantari si incasari cu destinatie speciala curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	71304	81963
	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	4734677	2010939
	Total pasive (rd.390 + rd.440 + rd.580)	590	22922956	23037804

SITUATIA DE PROFIT SI PIERDERE

de la pina la

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	010	27523075	27319617
Costul vinzarilor	020	15709392	15672962
Profit brut (pierdere bruta) (rd.010 - rd.020)	030	11813683	11646655
Alte venituri din activitatea operationala	040		28586
Cheltuieli de distribuire	050	46862	16306
Cheltuieli administrative	060	729327	964136

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Alte cheltuieli din activitatea operationala	070	384100	417394
Rezultatul din activitatea operationala: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10653394	10277405
Rezultatul din alte activitati: profit (pierdere)	090	10777	195996
Profit (pierdere) pina la impozitare (rd.080 + rd.090)	100	10664171	10081409
Cheltuieli privind impozitul pe venit	110	1291160	1178993
Profit net (pierdere neta) al perioadei de gestiune (rd.100 - rd.110)	120	9373011	8902416

SITUATIA MODIFICARILOR CAPITALULUI PROPRIU

de la pina la

Anexa 3

Nr. dno	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorari	Diminuari	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
1	Capital social si suplimentar					
	Capital social	010				
	Capital suplimentar	020				
	Capital nevarsat	030	0	0	0	0
	Capital neînregistrat	040				
2	Total capital social si suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
	Rezerve					
	Capital de rezerva	070				
	Rezerve statutare	080				
	Alte rezerve	090				
3	Total rezerve (rd.070 + rd.080 + rd.090)	100				
	Profit nerepartizat (pierdere neacoperita)					
	Corectii ale rezultatelor anilor precedenti	110	X			
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	120				
	Profit net (pierdere neta) al perioadei de gestiune	130	X			
4	Total profit nerepartizat (pierdere neacoperita) (rd.110 + rd.120 + rd.130 - rd.140 + rd.150)	160				
	Alte elemente de capital propriu, din care	170				
	Diferente din reevaluare	171				
	Subventii entitatilor cu proprietate publica	172				
	Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180				

SITUATIA FLUXURILOR DE NUMERAR

de la pina la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxuri de numerar din activitatea operationala			
Incasari din vinzari	010		
Plati pentru stocuri si servicii procurate	020		
Plati catre angajati si organe de asigurare sociala si medicala	030		
Dobînzî platite	040		
Plata impozitului pe venit	050		
Alte incasari	060		
Alte plati	070		
Fluxul net de numerar din activitatea operationala (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investitii			
Incasari din vînzarea activelor imobilizate	090		
Plati aferente intrarilor de active imobilizate	100		
Dobînzî incasate	110		
Dividende incasate	120		
Alte incasari (plati)	130		

Unitatea de masura: leu

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxul net de numerar din activitatea de investitii (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)			
140			
Fluxuri de numerar din activitatea financiara			
Incasari sub forma de credite si imprumuturi	150		
Plati aferente rambursarii creditelor si imprumuturilor	160		
Dividende platite	170		
Incasari din operatiuni de capital	180		
Alte incasari (plati)	190		
Fluxul net de numerar din activitatea financiara (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferente de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Date generale

Anexa 6

- Certificat de înregistrare a entității, eliberat de Camera Înregistrării de Stat.
- Numar de înregistrare Data Înregistrării Seria Numar
- Capital social înregistrat de Camera Înregistrării de Stat:
data , suma lei, inclusiv:
a) cota statutului lei,
b) cota detinatorilor a cel puțin 20% Incease lei.
Modificari ulterioare:
a) , suma lei, inclusiv cota statutului lei,
b) , suma lei, inclusiv cota statutului lei.
- Entitatile, activitatea carora necesita licenta, indica:
Licenta in vigoare:

Nr. Ord.	Numar	Data eliberarii	Termen de valabilitate	Tipul de activitate	Organul care a eliberat licenta
1					
- Numarul mediu scrisor al personalului in perioada de gestiune g persoane, inclusiv pe categorii:
1) personal administrativ g persoane,
2) muncitori persoane.
- Numarul personalului la 31 decembrie 2019 g persoane.
- Remunerarea personalului entitatii in perioada de gestiune 326523 lei.
- Remunerarea membrilor organelor de administrare, de conducere si supraveghere si alte angajamente aparute sau asumate in legatura cu pensile membrilor actuali sau ale fostilor membri ai acestor organe, pe categorii lei.
- Avansurile si creditile acordate membrilor organelor specificate la pct.7 lei, inclusiv rambursate lei.
1) valoarea de gaj lei,
2) valoarea contabila lei.
- Numarul actiunilor ordinare a finel perioadei de gestiune unitati.
- Profit net (pierdere neta) a perioadei de gestiune pentru o actiune ordinara:
1) profit lei,
2) pierdere lei.
- Dividende calculate pentru o actiune ordinara pentru perioada de gestiune:
1) platite lei,
2) planificate pentru plata lei.
- Valuta straina disponibila, recalculata in moneda nationala a Republicii Moldova - total lei, inclusiv lei, denumirea si codul valutei:

Nr. Ord.	lei	denumirea	codul valutei
1			
- Numarar legat - total lei.
In indurilie, in care se inscriu sumele de gaj, in toate coloanele prin fractie se reflecta:
a) la numarator - valoarea de gaj;
b) la numitor - valoarea contabila

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Creante, investitii financiare si datorii pe termen lung aferente fondatorilor nerezidenti

Tabelul 1

Indicatori	Cod rd./ cod tara	Sold la începutul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfîrșitul perioadei de gestiune
			Intrari / majorari	iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung - total						
010						
Creante comerciale, inclusiv pe tari:						
020						
1	2	3	4	5	6	7

1	2	3	4	5	6	7
Avansuri acordate, inclusiv pe tari:	030					
1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040					
1	2	3	4	5	6	7
Alte creante si investitii financiare, inclusiv pe tari:	050					
1	2	3	4	5	6	7
Datorii pe termen lung - total	060					
Datorii comerciale, inclusiv pe tari:	070					
1	2	3	4	5	6	7
Avansuri primite, inclusiv pe tari:	080					
1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	090					
1	2	3	4	5	6	7
Alte datorii, inclusiv pe tari:	100					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100
Col.7 = col.3+col.4-col.5-col.6

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Creante, investitii financiare si datorii pe termen lung aferente nerezidentilor, cu exceptia fondatorilor						
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
			Intrari / majorari	Iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung - total	010					
Creante comerciale, inclusiv pe tari:	020					
1	2	3	4	5	6	7
Avansuri acordate, inclusiv pe tari:	030					
1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040					
1	2	3	4	5	6	7
Depozite, inclusiv pe tari:	050					
1	2	3	4	5	6	7
Alte creante si investitii financiare, inclusiv pe tari:	060					
1	2	3	4	5	6	7
Datorii pe termen lung - total	070					
Datorii comerciale, inclusiv pe tari:	080					
1	2	3	4	5	6	7
Avansuri primite, inclusiv pe tari:	090					
1	2	3	4	5	6	7

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110
Col.9+10= col.(3+4) + col.5 - col.7 ± col.8

1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	100					
1	2	3	4	5	6	7
Alte datorii, inclusiv pe tari:	110					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.60
Rd.070= rd.080 + rd.090 + rd.100 + +rd.110
Col.7 = col.3+col.4-col.5-col.6

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Creante, investitii financiare si datorii curente aferente fondatorilor nerezidenti						
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari
					Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an
						Termenul expirat mai mult de un an
1	2	3	4	5	6	7
Creante si investitii financiare curente - total	010					
Creante comerciale, inclusiv pe tari:	020					
1	2	3	4	5	6	7
Avansuri acordate, inclusiv pe tari:	030					
1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040					
1	2	3	4	5	6	7
Alte creante si investitii financiare, inclusiv pe tari:	050					
1	2	3	4	5	6	7
Datorii curente - total	060					
Datorii comerciale, inclusiv pe tari:	070					
1	2	3	4	5	6	7
Avansuri primite, inclusiv pe tari:	080					
1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	090					
1	2	3	4	5	6	7
Datorii privind dividenzele calculate, inclusiv pe tari:	100					
1	2	3	4	5	6	7
Alte datorii, inclusiv pe tari:	110					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 - col.7 ± col.8

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Creante, investitii financiare si datorii curente aferente nerezidentilor, cu exceptia fondatorilor								
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune	
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an
								Termenul expirat mai mult de un an
1	2	3	4	5	6	7	8	9
Creante si investitii financiare curente - total	010							
Creante comerciale, inclusiv pe tari:	020							
1	2	3	4	5	6	7	8	9
Avansuri acordate, inclusiv pe tari:	030							
1	2	3	4	5	6	7	8	9
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040							
1	2	3	4	5	6	7	8	9
Depozite, inclusiv pe tari:	050							
1	2	3	4	5	6	7	8	9
Alte creante si investitii financiare, inclusiv pe tari:	060							
1	2	3	4	5	6	7	8	9
Datorii curente - total	070							
Datorii comerciale, inclusiv pe tari:	080							
1	2	3	4	5	6	7	8	9
Avansuri primite, inclusiv pe tari:	090							
1	2	3	4	5	6	7	8	9
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	100							
1	2	3	4	5	6	7	8	9
Alte datorii, inclusiv pe tari:	110							

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 - col.7 ± col.8

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Investitii financiare in strainatate si participarea nerezidentilor in capitalul social					
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Investitii financiare	010				
Cote de participatie si actiuni de pina la 10% inclusiv, in capitalul social al entitatilor nerezidente, inclusiv pe tari:	020				
1	2	3	4	5	6
Cote de participatie si actiuni de peste 10% in capitalul social al entitatilor nerezidente, inclusiv pe tari:	030				
1	2	3	4	5	6

1	2	3	4	5	6
Capital social	040				
Cote de participatie si actiuni de pina la 10% inclusiv, inclusiv pe tari:	050				
1	2	3	4	5	6
Cote de participatie si actiuni de peste 10%, inclusiv pe tari:	060				

Rd.010= rd.020 + rd.030
Rd.040= rd.050 + rd.060
Col.6 = col.3+col.4-col.5

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Venituri si cheltuieli aferente tranzactiilor cu nerezidentii					
Indicatori	Cod rd./cod tara	Perioada de gestiune			
		precedenta	curenta		
1	2	3	4		
Venituri - total	010				
Venituri aferente bunurilor procurate si vandute peste hotare fara trecerea frontierei de stat a Republicii Moldova, inclusiv pe tari:	020				
1	2	3	4		
Venituri din dobinzi aferente activitatii operationale si altor activitati, inclusiv pe tari:	030				
1	2	3	4		
Venituri din dividende si participati in alte entitati,inclusiv pe tari:	040				
1	2	3	4		
Venituri din decontarea datoriilor cu termenul de prescriptie expirat, inclusiv pe tari:	050				
1	2	3	4		
Alte venituri, inclusiv pe tari:	060				
1	2	3	4		
Cheltuieli - total	070				
Cheltuieli aferente bunurilor procurate si vandute peste hotare fara trecerea frontierei de stat a Republicii Moldova, inclusiv pe tari:	080				
1	2	3	4		
Cheltuieli privind dobinzile, inclusiv pe tari:	090				
1	2	3	4		
Cheltuieli si provizioane aferente creantelor comerciale si altor creante compromise, inclusiv pe tari:	100				
1	2	3	4		
Alte cheltuieli, inclusiv pe tari:	110				

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Bunuri ale nerezidentilor inregistrate in conturi extrabilantiere					
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Bunuri primite in baza contractelor de comision, inclusiv pe tari:	010				
1	2	3	4	5	6

6/12/2020

View BNS receipt | Declaratia electronica

Versiune de imprimare

Salvare

Recipisa 2

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1

Pentru perioada fiscala: A/2019

Data prezentarii: 31.03.2020

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 21.05.2020 10:13:29

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

Col.6 = col.3+col.4-col.5

Informațiile privind activele imobilizate

Anexa 7

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
A	1	2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuție	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200								
2.1 brevete și mărci	210								
2.2. licențe de activitate	220								
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuție	300								
4. Terenuri	400		x					x	
5. Mijloace fixe, total din care:	500								
5.1. clădiri	510								
5.2. construcții speciale	520								
5.3. mașini, utilaje, instalații de transmisie	530								
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente și inventar	550								
5.6. costuri ulterioare aferente obiectelor neluate în bilanș	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								
6. Resurse minerale	600								
7. Investiții imobiliare, total	700								

Persoanele responsabile de semnarea rapoartelor financiare ale entității*

* conform art.36 din Legea contabilității

Documente atașate - Notă explicativă (fișierul pdf)

Blisistem 2019.pdf

6/12/2020

Afișează recipisa | Declaratia electronica

Versiune de imprimare

Salvare

Recipisa

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1

Pentru perioada fiscala: A/2019

Data prezentarii: 31.03.2020

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 31.03.2020 17:42:37

https://declaratie-electronica.fisc.md/ro/declaration/11542429/receipt-bns?print=1

1/1

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2105690**

din
от **09.04.2021**

1. Destinația / Назначение

Pentru participare 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 Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de 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 24.04.2021

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef DDF Rîșcani

a DGAF mun.Chișinău
L.Ș/ M.П.

Executor: **Svetlana Slonovskaia**
Numele și prenumele/Фамилия и имя



Viorica CĂUȘ

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 09.04.2021 ora 10:51:57
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,27)

DECLARATION OF CONFORMITY

Forli, 18th January 2018

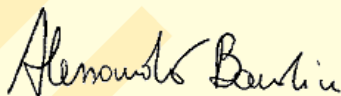
The devices named TOP TRACE & MEDISENSOR DISPOSABLE ELECTRODES FOR ECG (including models ST 50 RFI / RT 50 RFI & MEDISENSOR FS501-S) and the REUSABLE SUCTION CHEST AND CLAMP ELECTRODES have been produced by the company Ceracarta Spa on the basis of the essential requirements, see enclosure I of the directive 93/42/CEE, as prescribed in attachment VII of the above directive.

The writing company Ceracarta Spa located in Via Secondo Casadei n° 14, 47122 Forli, manufacturer of above listed DISPOSABLE & REUSABLE ELECTRODES declares under its own responsibility that such devices satisfy all the requirements of directive 93/42/CEE as amended by 2007/47/EC, about medical devices and in particular that:

- the Dispositives in object satisfy the essential requirements as in enclosure I of Directive 93/42/CEE;
- the Dispositives in object must be considered as belonging to Class I;
- the manufacturer has prepared and keeps the technical files updated in accordance with enclosure VII, section 3 of the directive itself;
- such documentation is available at the headquarters of Ceracarta, for any reference by the entitled bodies.

Sincerely,

CERACARTA SPA
Bandini Alessandro



Ceracarta S.p.A. Via Secondo Casadei, 14 - 47122 Forli ITALY
Tel: +39.0543780055 Fax: +39.0543781404
<http://www.ceracarta.it> info@ceracarta.it



EN ISO 13485:2012



www.imq.it

**CERTIFICATO N.
CERTIFICATE N. 9124.CRC4**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / OPERATIVE UNITS

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD
ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrodes for ECG. Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	1999-07-20	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A

Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo
del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment
of the entire management System within three years



Organismo di Certificazione Federato CISQ
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CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management
system Certification Bodies.



*IQNet, the association of the world's first class
certification bodies, is the largest provider of management
System Certification in the world.
IQNet is composed of more than 30 bodies and counts
over 150 subsidiaries all over the globe.*



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ALLEGATO N. 9124.CRC4-1 ANNEX N.



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CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLÌ (FC)

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi.

Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG.

Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrodes for ECG.

Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPlicitARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	1999-07-20	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornaghi



www.cisq.com



SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC. Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9124.CRC4
This document is a part of certificate n. 9124.CRC4

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

Organismo di Certificazione Federato CISQ
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CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.



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ALLEGATO N. **9124.CRC4-2**
ANNEX N.



*IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.
IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.*

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPlicitARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9124.CRC4
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.CRC4

DATE:	PRIMA CERTIFICAZIONE <i>FIRST CERTIFICATION</i>	EMISSIONE CORRENTE <i>CURRENT ISSUE</i>	SCADENZA <i>EXPIRY</i>
	1999-07-20	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9124.CRC4
This document is a part of certificate n. 9124.CRC4

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years



Organismo di Certificazione Federato CISQ
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CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.



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IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

**CERTIFICATO N.
CERTIFICATE N. 9190.CRC3**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA
VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / OPERATIVE UNITS

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID).

Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrodes for ECG.

Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION 2002-11-26	EMISSIONE CORRENTE CURRENT ISSUE 2020-09-29	SCADENZA EXPIRY 2023-10-07
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IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.



www.imq.it

ALLEGATO N. 9190.CRC3-1 ANNEX N.



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLÌ (FC)

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori.

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrodes for ECG. Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPlicitARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	2002-11-26	2020-09-29	2023-10-07


IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



www.cisq.com



SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

Organismo di Certificazione Federato CISQ
www.imq.it

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.



www.imq.it

ALLEGATO N. 9190.CRC3-2
ANNEX N.



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLÌ (FC)

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	2002-11-26	2020-09-29	2023-10-07

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ has issued an IQNet recognized certificate that the organization:

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLÌ (FC)

VIA GRAMADORA 12/14 - 47122 FORLÌ (FC)

has implemented and maintains a

Quality Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrodes for ECG. Production management and placing on the market of electrodes for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: 2020 - 09 - 29

Expires on: 2023 - 10 - 07

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 112265



Alex Stoichitoiu
President of IQNET



Ing. Mario Romersi
President of CISQ

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



Certificate

No. Q5 105557 0001 Rev. 00

Holder of Certificate: **Meril Endo Surgery Pvt. Ltd.**
Third floor, E1- E3, Meril Park
Survey No 135/2/B & 174/2, Muktanand Marg, Chala
396191 Vapi, Gujarat
INDIA

Facility(ies): Meril Endo Surgery Pvt. Ltd.
Third floor, E1- E3, Meril Park , Survey No 135/2/B & 174/2,
Muktanand Marg, Chala, 396191 Vapi, Gujarat, INDIA

Meril Endo Surgery Pvt. Ltd
Type A-2, Shed No. 11, Survey No. 725/P, Phase – I, GIDC,
396195 Vapi, Gujarat, INDIA

Meril Endo Surgery Pvt. Ltd
Plot No 688/10 & 11, Siddivinayak Industrial Estate, Somnath
Road, 396210 Daman, INDIA

Certification Mark:



Scope of Certificate: Design, Development, Production, Testing, Storage, Sales and Distribution of Sterile / Non-sterile Endo Surgical Products e.g., Bulk and Finished Surgical Sutures, Polytetrafluoroethylene Pledgets, Sutures with Polytetrafluoroethylene Pledgets, Contraceptive Devices, Surgical Meshes, Mesh Fixation Devices, Bone Wax, Umbilical Cotton Tape, Surgical Kits, Surgical Staplers and Staples, Tourniquet Devices, Disposable Endoscopic Trocars, Ligating Clips, Surgical Haemostats, Skin Adhesives, Surgical Adhesives, Sealants & Surgical Needles”

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: IND2019074
Valid from: 2020-03-30
Valid until: 2023-03-29

Date, 2020-03-30

Christoph Dicks
Head of Certification/Notified Body

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-1929401

Manufacturer: MERIL ENDO SURGERY PVT. LTD.
Third Floor, E1-E3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg,
Chala, Vapi – 396 191, Gujarat, INDIA

Product(s): (1) Non-Absorbable, Braided Coated Poly(Ethylene Terephthalate) Surgical Suture
(2) Non-Absorbable, Monofilament Polyamide Surgical Suture
(3) Non-Absorbable, Monofilament Polypropylene Surgical Suture
(4) Non-Absorbable, Braided Coated Silk Surgical Suture
(5) Non-Absorbable, Monofilament Stainless Steel Surgical Suture

Model(s): Product specifications are stated on the second page.

Reference Report No: MM0755-P001-R01, MM0755-P001-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2024-05-26.

Issue Date: 2019-10-21



Rukiye BALKAN
Deputy General Manager

SZUTEST

Certificate Number: 2195-MED-1929401

Product Specifications

Product Categories	Type (Models)	Generic Name
(1) Non-Absorbable, Braided Coated Poly(Ethylene Terephthalate) Surgical Suture	MERICRON XL™	Sterile Non-Absorbable Poly(Ethylene Terephthalate) Surgical Suture
	Aspiron™	Sterile Non-Absorbable Poly(Ethylene Terephthalate) Surgical Suture
	MERICRON XL™ P	Sterile Non-Absorbable Poly(Ethylene Terephthalate) Surgical Suture with PTFE Pledget
(2) Non-Absorbable, Monofilament Polyamide Surgical Suture	FILAMIDE™	Sterile Non-Absorbable Polyamide Surgical Suture
	Aspiron™	Sterile Non-Absorbable Polyamide Surgical Suture
(3) Non-Absorbable, Monofilament Polypropylene Surgical Suture	FILAPROP™ P	Sterile Non-Absorbable Polypropylene Surgical Suture with PTFE Pledget
(4) Non-Absorbable, Braided Silk Surgical Suture	FILASILK™ REEL	Non-Sterile Non-Absorbable Silk Surgical Suture
(5) Non-Absorbable, Monofilament Stainless Steel Surgical Suture	MERISTEEL™	Sterile Non-Absorbable Stainless Steel Surgical Suture



SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE

Szutest.com.tr

EC Certificate

Full Quality Assurance System

Certificate No.:
245506-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-499089-2014-MSL-IND

Valid Until:
27 May 2024

This is to certify that the quality system of:

Meril Endo Surgery Pvt Ltd

Third Floor, E1- E3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg,
Chala, Vapi, Gujarat, India - 396191

For design, production and final product inspection/testing of:

Sterile / non - sterile surgical sutures with and without needle

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 16 July 2019



For:
DNV GL PRESAFE AS



Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate

Full Quality Assurance System

Certificate No.:
245506-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-499089-2014-MSL-IND

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB 0434) Certificate no: 151561-2014-CE-IND-NA Rev 3.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-11-15
1.0	Remove of Polypropylene Mesh	2018-01-08
2.0	Recertification and reduction in scope	2019-07-16

Products covered by this Certificate:

Product Description	Product Name	Class
Absorbable Sutures	<ul style="list-style-type: none"> Megasorb™ / Aspiron™ Polyglycolic acid Braided coated Polyglycolic acid suture Mitsu™ / Aspiron™ Polyglactin 910 and Mitsu FST™ / Aspiron™ Polyglactin 910 FST. Braided coated Poly (glycolide/l-lactide) suture Filaxyn™ / Aspiron™ Polydioxanone suture. Monofilament Poly (p-dioxanone) suture Filapron™ / Aspiron™ Polyglecaprone 25 suture. Monofilament poly (glycolide-co-caprolactone) suture 	III*
Non-Absorbable Sutures	<ul style="list-style-type: none"> Filaprop™ / Aspiron™ Polypropylene Blue Monofilament Polypropylene Suture 	III**

EC Certificate

Full Quality Assurance System

Certificate No.:
245506-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-499089-2014-MSL-IND

Valid Until:
27 May 2024

*Design assessment is covered by a separate EC-Design Examination Certificate No.: 245507-2017-CE-IND-NA-PS Rev. 2

**Design assessment is covered by a separate EC-Design Examination Certificate No.: 245508-2017-CE-IND-NA-PS Rev. 2

Sites covered by this certificate

Site Name	Address
Meril Endo Surgery Pvt Ltd	Third Floor, E1- E3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, Gujarat, India - 396191

EU Representative

OBELIS S.A

Bd. Général Wahis, 53, 1030 Brussels, Belgium. Tel: +32.2.732.59.54. Fax: +32.2.732.60.03

E-mail: mail@obelis.net, www.obelis.net

EC Certificate

Full Quality Assurance System

Certificate No.:
245506-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-499089-2014-MSL-IND

Valid Until:
27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate



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 Inc**

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 Copenhagen
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 Österreich 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
Céptület 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 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

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

Registration No.: HD 60147050 0001

Report No.: 26300270 016

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 60100981 0001

Expiry Date: 2024-05-26

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: 2020-02-25

Date: 2020-02-25



Notified Body


Sebastian Mnisek

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60147050 0001
Report No.: 26300270 016

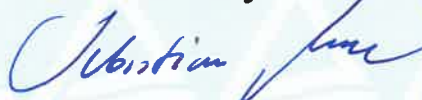
Manufacturer: Grena Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

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
- Staples cartridge for reusable linear cutting staplers
- Ligating clip cartridge to be used with reusable automatic clip appliers

Date: 2020-02-25

Notified Body



Sebastian Mniszek



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60147050 0001
Report No.: 26300270 016

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

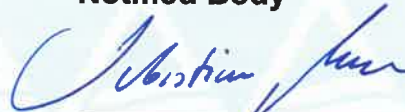
Site included:

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

Activity: Desing, development and manufacture

Date: 2020-02-25

Notified Body



Sebastian Mniszek



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, manufacture 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 13485:2016

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

Effective Date: 2020-02-25
Certificate Registration No.: SX 60147335 0001
An audit was performed. Report No.: 26300270 015
This Certificate is valid until: 2021-04-13

Certification Body



Date 2020-02-25




Sebastian Mnisek

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 60147335 0001
Report No.: 26300270 015

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

Scope:

Site included:

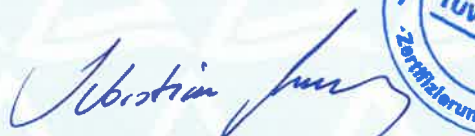
Grena Ltd.
Chelsea House
Chelsea Street
Nottingham NG7 7HP
United Kingdom

Activity: Design and development, manufacture
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: 2020-02-25



Sebastian Mniszek



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

