



REPUBLICA MOLDOVA

# LICENȚĂ

**Seria A MMII**

**Nr. 044322**

Denumirea autorității de licențiere

Camera de Licențiere

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

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

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

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

12.08.2010 MD 0101250

Numărul de înregistrare a întreprinderii sau IDNO

1010600028048

Codul fiscal

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

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

Data eliberării licenței

4 octombrie 2010

Reperfectată: 1)19.10.2012; 2)14.05.2014

Valabilă pînă la

4 octombrie 2015

Prelungită pînă la: 03.10.2020

**Semnătura conducătorului  
autorității de licențiere**

**Director al Camerei de Licențiere**

**Valentin GUZNAC**



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



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

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

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

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

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

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza  
Tel. 43-45-96

REPUBLICA



MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal  
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

**Svirepova Ludmila, registrator**

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

*L. Svirepova*  
semnătura

MD 0101250





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

**EXTRAS**  
din Registrul de stat al persoanelor juridice

nr. 14419 din 11.07.2016

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

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

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

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

Data înregistrării de stat: **12.08.2010.**

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

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

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

Capitalul social: **5400 lei.**

**Administrator: POIATA VITALIE, IDNP 0983103892591,**

Asociați:

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

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

Specialist principal  
tel. 022-266-252

**Lazari Aliona**



## **Lista fondatorilor Biosistem-mld SRL**

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

**SITUAȚIILE FINANCIARE**

pentru perioada 01.01.2017 31.12.2017

Entitatea BIOSISTEM MLD SRL  
(Denumirea completă)

40717392 1010600028048  
(Cod CUIIO) (Cod IDNO)

Sediul: MD MD-2001 MUN.CHIȘINĂU; MUN.CHIȘINĂU SEC.RÎȘCANI 150  
(Cod poștal) Raionul (municipiul, UTA); Localitatea Albisoara, 16, 1, of.7 Cod CUATM

Activitatea principală: strada, nr, bl. 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 și coordonatele al contabilului-șef: Dl (dna) +37322808719 Unitatea de măsură: leu  
Tel. +37369463619

Anexa 8

**Notă informativă privind veniturile și cheltuielile clasificate după natură**

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vânzări	010	15.623.709	20.497.176
Alte venituri din activitatea operațională	020		500
Venituri din alte activități	030	368.943	361.872
<b>Total venituri</b> (rd.010 + rd.020 + rd.030)	040	15.992.652	20.859.548
Variația stocurilor	050		
Costul vânzărilor	060	9.960.221	11.372.168
Cheltuieli privind stocurile	070	306.856	118.975
Cheltuieli cu personalul privind remunerarea muncii	080	129.850	169.200
Contribuții de asigurări sociale de stat obligatorii și prime de asigurare obligatorie de asistență medicală	090	35.709	46.530
Cheltuieli cu amortizarea și deprecierea activelor imobilizate	100	7.389	90.494
Alte cheltuieli	110	306.855	548.183
Cheltuieli din alte activități	120	289.432	558.776
<b>Total cheltuieli</b> (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

## BILANŢUL

Anexa 1

la 31.12.2017

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

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

## SITUAȚIA DE PROFIT ȘI PIERDERE

Anexa 2

de la 01.01.2017 pînă la 31.12.2017

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

## SITUAȚIA MODIFICĂRII CAPITALULUI PROPRIU

Anexa 3

de la 01.01.2017 pînă la 31.12.2017

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

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

Anexa 4

de la 01.01.2017 pînă la 31.12.2017

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

**Date generale**

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

14. Numerar legat – total \_\_\_\_\_ lei.

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

Anexa 7

**Informațiile privind activele imobilizate**  
de la 01.01.2017, până la 31.12.2017

Indicatori	Nr. rînd	Existența la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieșirea în cursul perioadei (la costul de intrare)	Existența la sfîrșitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrșitul perioadei	Deprecierea acumulată la sfîrșitul perioadei
		2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuție	10C								
2. Imobilizări corporale în utilizare, total inclusiv:	20C	3.25C	81.3				3.25C	1.463	
2.1. brevete și mărci	22C	3.25C	81.3				3.25C	1.463	
2.2. licențe de activitate	23C								
2.3. programe informatice	30C								
3. Imobilizări corporale în curs de execuție	40C		X					X	
5. Mijloace fixe, total din care:	500	205.204	9.679		796.422	6.100	995.526	90.823	
5.1. clădiri	51C								
5.2. construcții speciale	52C								
5.3. mașini, utilaje, instalații de transmisie inclusiv: tehnică de calcul	53C	186.815	8.500		796.422	6.100	977.141	85.929	
5.4. mijloace de transport	54C								
5.5. instrumente și inventar	55C								
5.6. costuri aferente obiectelor neînregistrate în bilanț	56C								
5.7. mijloace fixe primite în leasuri financiare	57C								
5.8. mijloace fixe primite în gestiune economică	58C								
5.9. alte mijloace fixe	59C	18.385	1.379				18.385	6.894	
6. Resurse minerale	600								
7. Investiii imobiliare, total	700								

**Recipisa de primire a raportului**

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

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

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

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



**CERTIFICAT**  
**privind lipsa sau existența restanțelor față de bugetul public național**

Nr.  
№ 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
<b>BIOSISTEM MLD S.R.L.</b>	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. Serv. Riscani*  
Funcția/Dолжность

*[Signature]*  
Semnătura/Подпись

*Sna Stoian*  
Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: *[Signature]*  
Numele și prenumele/Фамилия и имя



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.: 38

TIP.DOC. 1

DATA EMITERII:5 februarie 2019

PLATITI: 200-00

LEI: Doua Sute lei 00 bani

PLATITOR: (R) "BIOSISTEM  
MLD" S.R.L.

CONTUL DE PLATI/CODUL IBAN  
MD95ML000000002251429243  
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR

CODUL BANCII:

BC"Moldindconbank"S.A. fil."Invest" Chisinau

:MOLDMD2X329:

BENEFICIAR (R) IMSP ACSR AG  
RM (Spital)

CONTUL DE PLATI/CODUL IBAN  
MD25ML000000002251806281  
CODUL FISCAL :1006601003968 /

PRESTATORUL BENEFICIAR

CODUL BANCII:

BC"Moldindconbank"S.A.

:MOLDMD2X

DESTINATIA PLATII: Pentru setul documente:  
lor de atribuire" sau "Pentru garantia p:  
entru oferta la licitatie publică nr. 21:  
004574 din 07.02.2019

TIPUL TRANSFERULUI  
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:05/02/2019

: SEMNATURILE

DATA EXECUTARII:05/02/2019 12:47:3

: EMITENTULUI

CONDUCATOR: Web "BIOSISTEM MLD" SRL Director

MIIGQYJKoZlIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:

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DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:  
gNVBAoTEUJpb3Npc3RlbnSBNTEQgU1JMMRiWEAYDVQQLEwkwNjkyMDAzMTQxZFA

(semnatura electronica)

CONTABIL-SEF: Web "BIOSISTEM MLD" SRL Contabil

MIIGUgYJKoZlIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:  
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:  
S1b3DQEBCwUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:  
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjYyOFowfjY4xCzAJBgNVBAYTAk1EMScw:  
YDVQQKEEx5NzWRlY29yIFNSTCwgQmlvc2lzdGVtIElMRCBTUkwxEjAQBGNVBAsT

L.S.

(semnatura electronica)

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

SEMNATURA PRESTATORUL

L.S.

MOTIVUL REFUZULUI

L.S.

SEM NATURA BANCII :

R/QMPenVevYSqg1G9mk2DySSpLJO338LqgMLpzDUNQ2j5IXXlM3tUzwCBpEN/Eenm  
dFV0TKozHxovkIaFXXYdUPkAY1JG5XpJkJv0f8MA1/KOTpFkhTiefLETzgNTUcVs7  
gi1n1FMVXQtVRBt825q00vmU6HZpuRbPKHWinXW5JlhoJi87lpDwnBVomOdjRM3Hr  
GZ8Hdt8kI/egTrpX1Cxq1RtT4cjqaFqAWVC+tZc+3C2HZkk+Aizkvq9JpL8oTxSYV  
x0tgx6INwtlWrfbFU5IaQbXAJVxZYAO/Uvm/cTEyQQKN2H1XrM0z1A0EXQ21IxHvi  
0Ua9EN7SatJ2kLpzQ==



# C E R T I F I C A T E

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

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

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

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

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

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

Certificate Number : M.2016.106.6949

Report Number : MD.3135.IB

Initial Assessment Date : 20.05.2016

Registration Date : 25.08.2016

Revision Date /No : 23.11.2016/01

Expiry Date : 24.08.2021

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

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

CE  
2292



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76

E-mail: [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udemltd.com.tr](http://www.udemltd.com.tr)



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

Date of issue : 15 February 2017

TO WHOM IT MAY CONCERN

HEALTH CERTIFICATE  
Free Sales Certificate

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

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

Sincerely Yours

**Yalçın SOYSAL, MD.**  
**Head of Medical Device Department**



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

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

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

Page 1/6

## PRODUCT LIST

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

**Yalçın SOYSAL, MD.**  
Head of Medical Device Department

## PRODUCT LIST

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

**Yalçın SOYSAL, MD.**  
Head of Medical Device Department

## PRODUCT LIST

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

**Yalçın SOYSAL, MD.**  
Head of Medical Device Department



## PRODUCT LIST

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

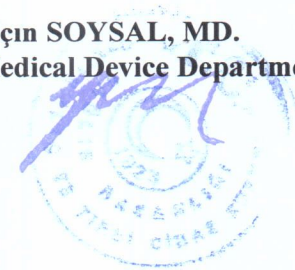
**Yalçın SOYSAL, MD.**  
Head of Medical Device Department

## PRODUCT LIST

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

End Of Product List  
15 February 2017

**Yalçın SOYSAL, MD.**  
**Head of Medical Device Department**





# Certificate of Registration

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

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

complies with the requirements of

**EN ISO 13485:2012**

This certificate is valid concerning all activities related to:

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

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

MD-0751  
 Certificate No.

Oct. 28, 2016  
 Date of this Certificate

Nov. 25, 2017  
 \*Next Audit Due Date

Nov. 26, 2015  
 Date of Initial Registration

Nov. 25, 2018  
 Certification Expiry Date

  
 Managing Director/Director



**TRANSPACIFIC CERTIFICATIONS LIMITED**

Website : [www.tclcertifications.com](http://www.tclcertifications.com) E-mail : [info@tclcertifications.com](mailto: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.



www.imq.it

CERTIFICATO N.  
CERTIFICATE N. 9190.CRC3

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

**CERACARTA SPA**

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

UNITA' OPERATIVE / OPERATIVE UNITS

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

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

**ISO 9001:2008**

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. Sviluppo e 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. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods 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 9001:2008 possono essere ottenute consultando l'organizzazione  
*Further clarifications regarding the applicability of ISO 9001:2008 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
	2002-11-26	2017-10-13	2020-10-07

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 9001:2015 entro il 2018/09/14;  
in caso contrario, il presente certificato cesserà la propria validità in tale data  
The Organization shall obtain the certification according to ISO 9001:2015 within 2018/09/14;  
otherwise the validity of this certificate will expire

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

Data di scadenza del precedente ciclo di certificazione: 2017-10-07  
Data di conclusione dell'audit di rinnovo: 2017-10-11  
Data della decisione di rinnovo: 2017-10-13



IAF: 07, 09, 19, 29

SGQ N°005A, SGA N°006D, SCR N°005F,  
SSI N°003G, FSM N°007I, SGE N°006M,  
EMAS N°003P, PRD N°005B, PRS N°008C,  
ISP N°003E, LAB N°012I, LAT N°002I  
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

I processi riconducibili a settori IAF sottolineati risultano non ancora coperti da accreditamento  
Processes related to underlined IAF sectors are not yet covered by accreditation  
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.

CISQ is a member of



THE INTERNATIONAL CERTIFICATION NETWORK  
www.iqnet-certification.com

*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.*



www.cisq.com



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**CISQ/IMQ** as an IQNet Partner hereby states that the organization

## **CERACARTA SPA**

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

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. Development and 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 9001:2008 requirements may be obtained by consulting the organization*

has implemented and maintains a  
**Quality Management System**  
which fulfills the requirements of the following standard

## **ISO 9001:2008**

Issued on: **2017 - 10 - 13**

First issued on: **2002 - 11 - 26**

*for the validity date, please refer to the original certificate\* issued by IMQ*

Registration Number: IT - 112265



Alex Stoichitoiu  
President of IQNET



Ing. Claudio Provetti  
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 FCAV Brazil  
FONDONORMA Venezuela ICONTEC Colombia Inspecta Certification Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland  
Quality Austria Austria RR Russia SIGE México SII Israel SIQ Slovenia SIRIM QAS International Malaysia  
SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey Vinçotte Belgium YUQS Serbia  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

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

\*\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



www.imq.it

CERTIFICATO N.  
CERTIFICATE N. 9124.CRC4

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

**CERACARTA SPA**

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

UNITA' OPERATIVE / OPERATIVE UNITS

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

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

**EN ISO 13485:2012**

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. Sviluppo e 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. Development and 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 EN ISO 13485:2012 possono essere ottenute consultando l'organizzazione  
Further clarifications regarding the applicability of EN ISO 13485:2012 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

<b>DATE:</b>	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	1999-07-20	2017-10-13	2020-10-07

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 13485:2016 entro il 2019/02/28;  
in caso contrario, il presente certificato cesserà la propria validità in tale data  
The Organization shall obtain the certification according to ISO 13485:2016 within 2019/02/28;  
otherwise the validity of this certificate will expire

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

Data di scadenza del precedente ciclo di certificazione: 2017-10-07  
Data di conclusione dell'audit di rinnovo: 2017-10-11  
Data della decisione di rinnovo: 2017-10-13

CISQ is a member of



*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.*



SGQ N°005A, SGA N°006D, SCR N°005F,  
SSI N°003G, FSM N°007I, SGE N°006M,  
EMAS N°003P, PRD N°005B, PRS N°008C  
ISP N°063E, LAB N°0121, LAT N°021

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

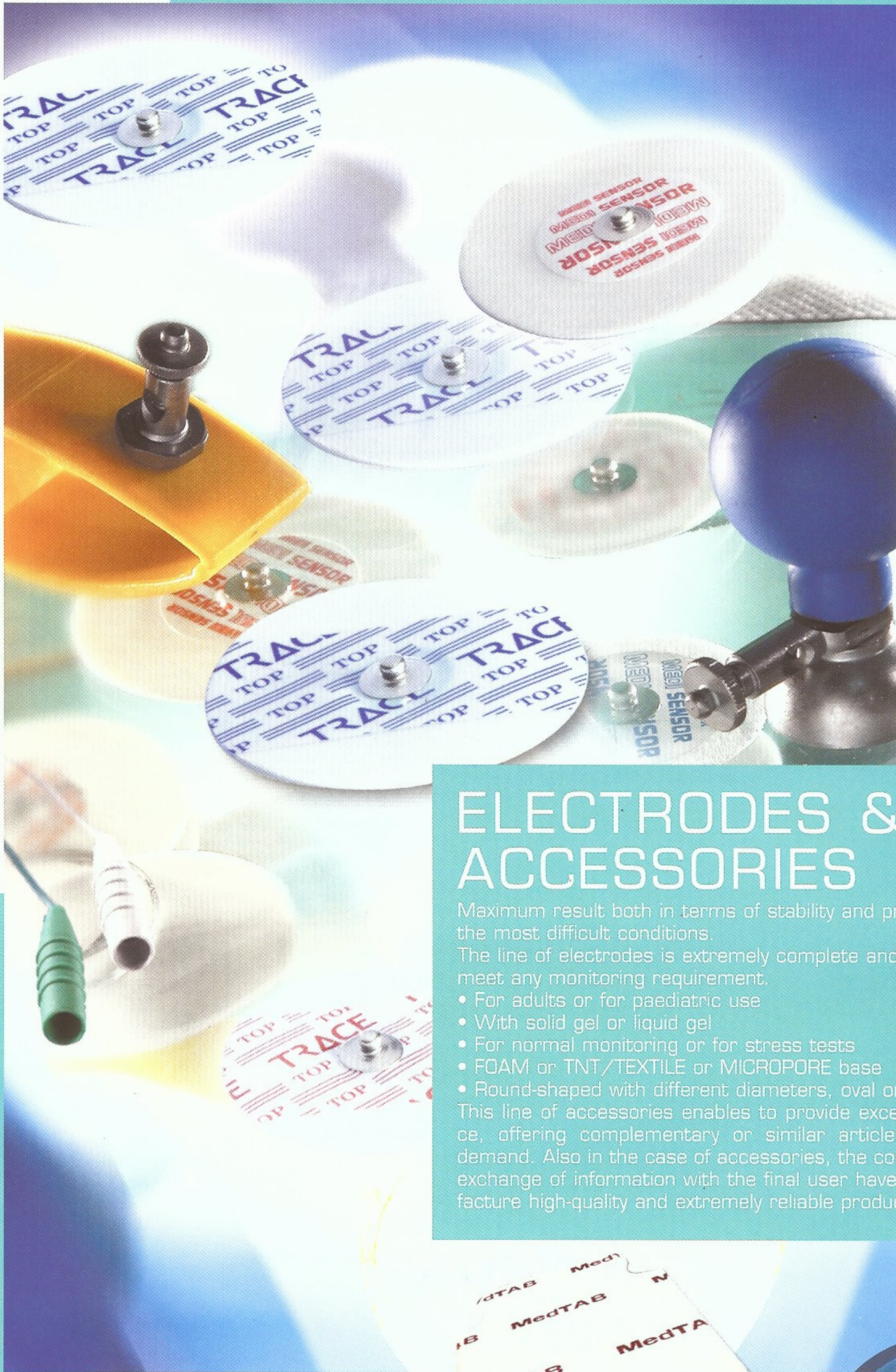
La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale  
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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.cisq.com



## ELECTRODES & ACCESSORIES

Maximum result both in terms of stability and precision, also under the most difficult conditions.

The line of electrodes is extremely complete and makes it possible to meet any monitoring requirement.

- For adults or for paediatric use
- With solid gel or liquid gel
- For normal monitoring or for stress tests
- FOAM or TNT/TEXTILE or MICROPORE base
- Round-shaped with different diameters, oval or rectangular

This line of accessories enables to provide excellent customer service, offering complementary or similar articles that are in great demand. Also in the case of accessories, the continuous research and exchange of information with the final user have allowed us to manufacture high-quality and extremely reliable products.



# CERACARTA

...for over  
**50**  
 years  
 CERACARTA  
 Italy  
 since... 1961

## MONITORING & RESTING ECG'S



**NM 50 RFI**

Ø50 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

**NM 55 RLI**

Ø55 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Liquid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

25 pcs / pouch - 500 pcs / box - 6000 pcs / carton

The most typical sizes. The most demanded supports. A proved quality always useful.



**NM 42 DFI**

45x42 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

**NM 3642 OFI**

42x36 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

Two multifunctional models: suitable for adult and pediatric ECG's.



**NP 30 RFI**

Ø30 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

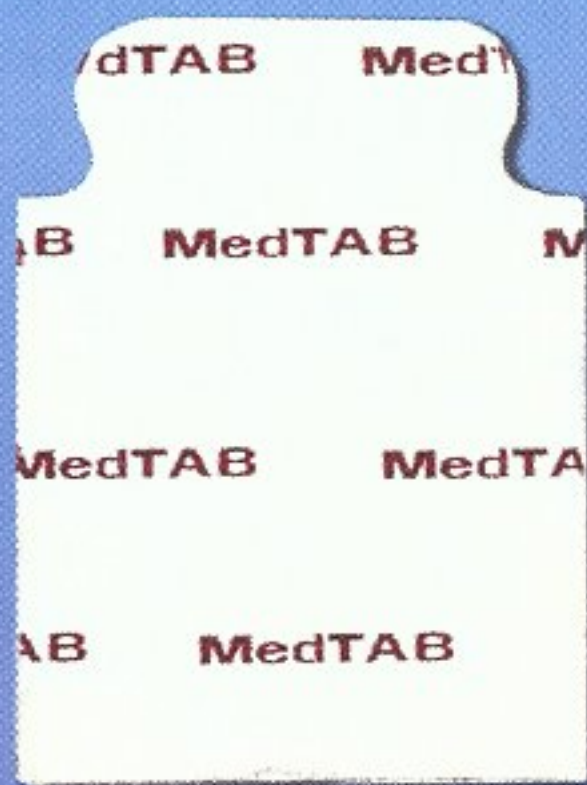
30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

The classical and largely used electrode for pediatric ECG's. Excellent quality ensured also on "critical" patients.

**NM 2844 RFS**

28x44 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

30 pcs / pouch - 600 pcs / box - 7200 pcs / master carton



**MEDTAB**

23x34 mm.	<b>Dimensions</b>
Silicone coated pet film	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl	<b>Sensor</b>

100 pcs / pouch - 500 pcs / box - 5000 pcs / carton

This electrode entirely replaces suction chests and clamps to patient's advantage both in terms of hygiene and health.

**NM 2844 FBI**

28x44 mm.	<b>Dimensions</b>
Foam	<b>Backing</b>
Solid	<b>Gel</b>
Ag/AgCl - Banana plug	<b>Sensor</b>

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton





## STRESS TEST



ST 50 RFI

Ø 50 mm.

**Dimensions**

Foam

**Backing**

Solid

**Gel**

Ag/AgCl

**Sensor**

ST 50 RLI

Ø 50 mm.

Foam

Liquid

Ag/AgCl



30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

**Packaging**

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

The most suitable electrodes for ECG's under difficult conditions.  
Easy to apply and use • Strong adhesiveness • Do not irritate the skin • Highly conductive gel

## HOLTER/LONG MONITORING



NM 55 TNI

Ø 55 mm.

**Dimensions**

TNT

**Backing**

Solid

**Gel**

Ag/AgCl

**Sensor**

RT 50 RFI

Ø 50 mm.

Foam

Solid

Carbon



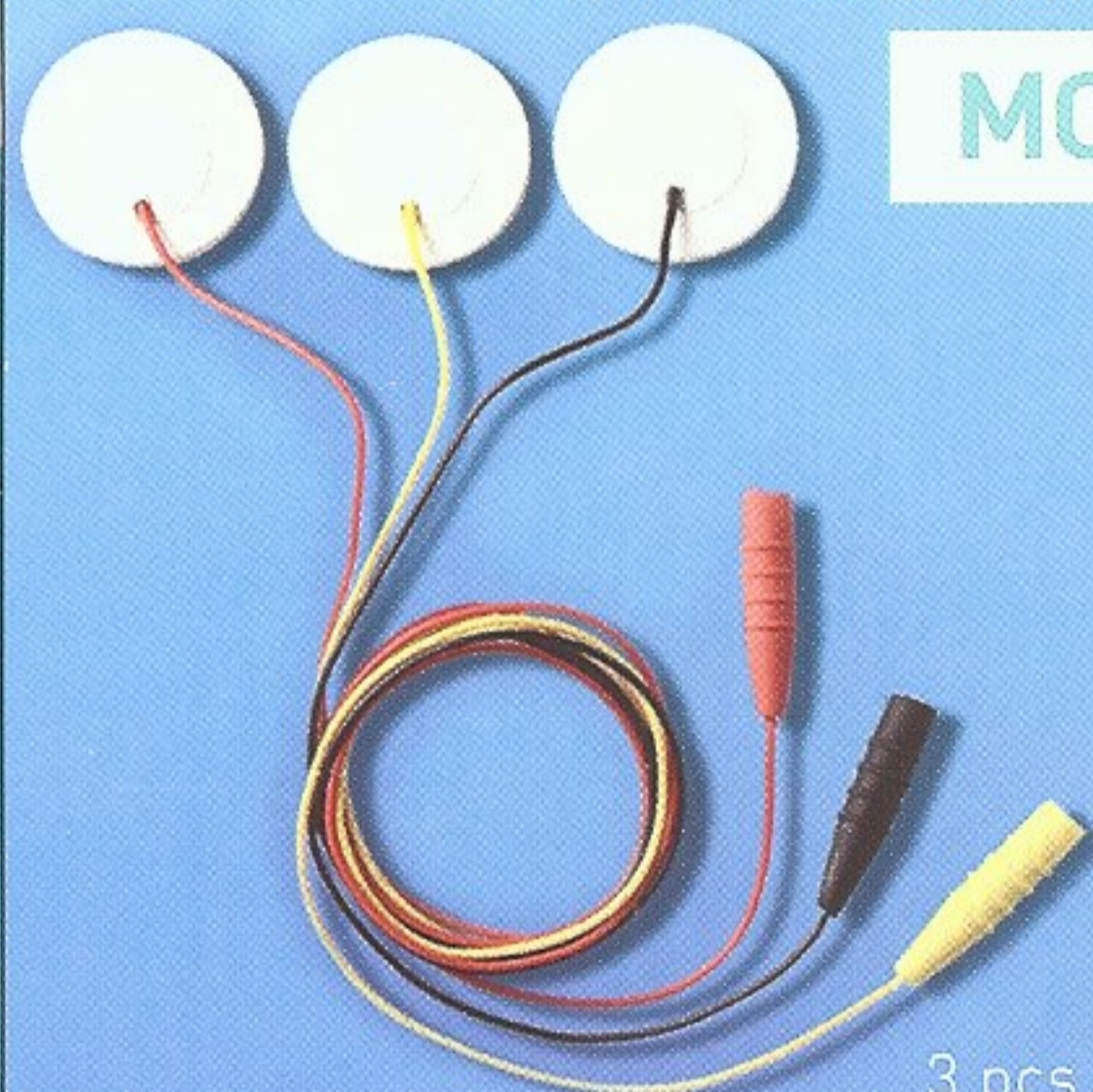
30 pcs / pouch - 600 pcs / box  
- 7200 pcs / carton

**Packaging**

30 pcs / pouch - 600 pcs / box - 7200 pcs / carton

When a larger adhesive surface is mandatory for an excellent examination. Easy to apply and use • Strong adhesiveness • Do not irritate the skin • Highly conductive gel

## MONITORING / PRE-WIRED ELECTRODES



RE 30 LWF

30 mm.  
female 4 mm

**Dimensions**

Foam

**Backing**

Solid

**Gel**

Ag/AgCl

**Sensor**

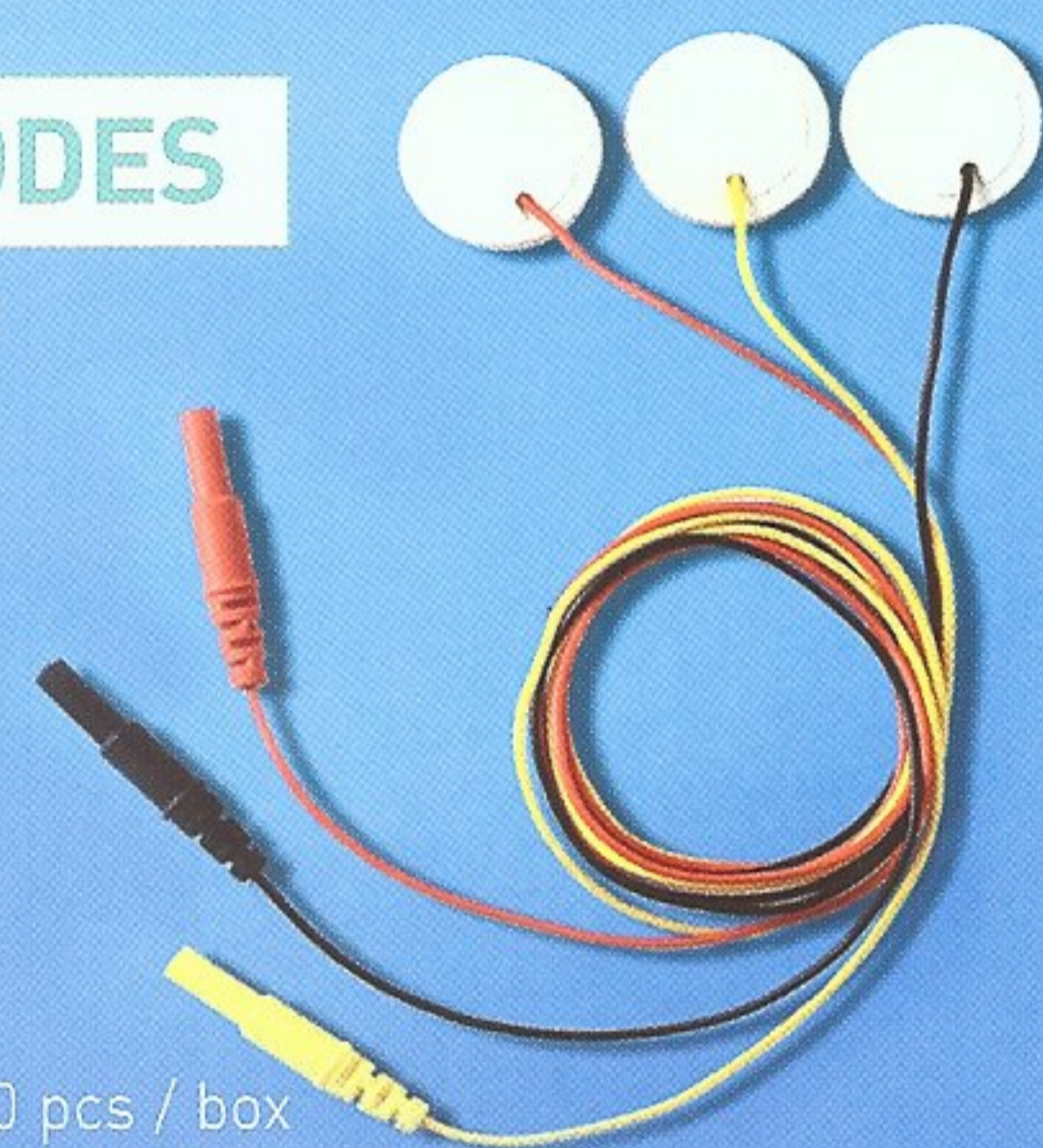
RE 22 LWS

22 mm.  
safety 1,55 mm

Foam

Solid

Ag/AgCl



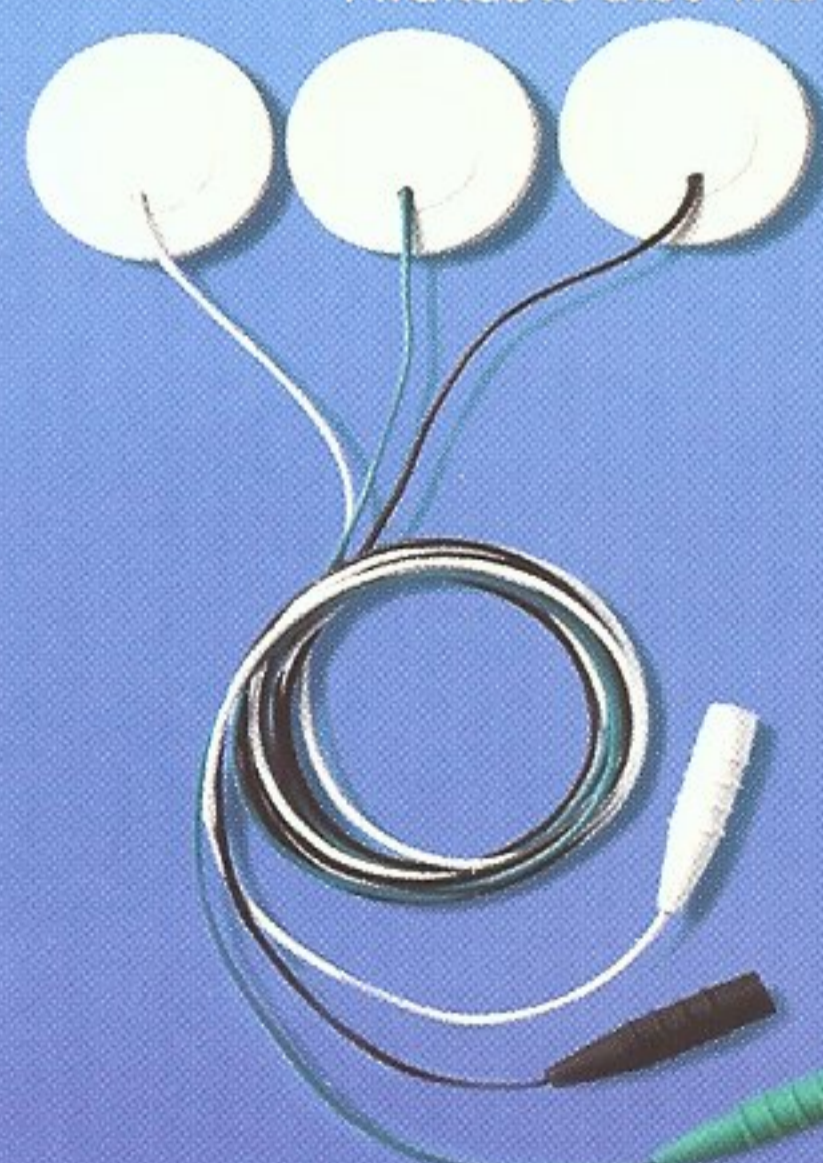
3 pcs / pouch - 300 pcs / box

**Packaging**

3 pcs / pouch - 300 pcs / box

Available also with 22 mm diameter Model RE 22 LWF  
(with 4 mm female plug)

Available also with 30 mm diameter Model RE 30 LWS  
(with 1,55 mm safety plug)



RT 30 LWF

30 mm.  
female 4 mm

**Dimensions**

Foam

**Backing**

Solid

**Gel**

Carbon

**Sensor**

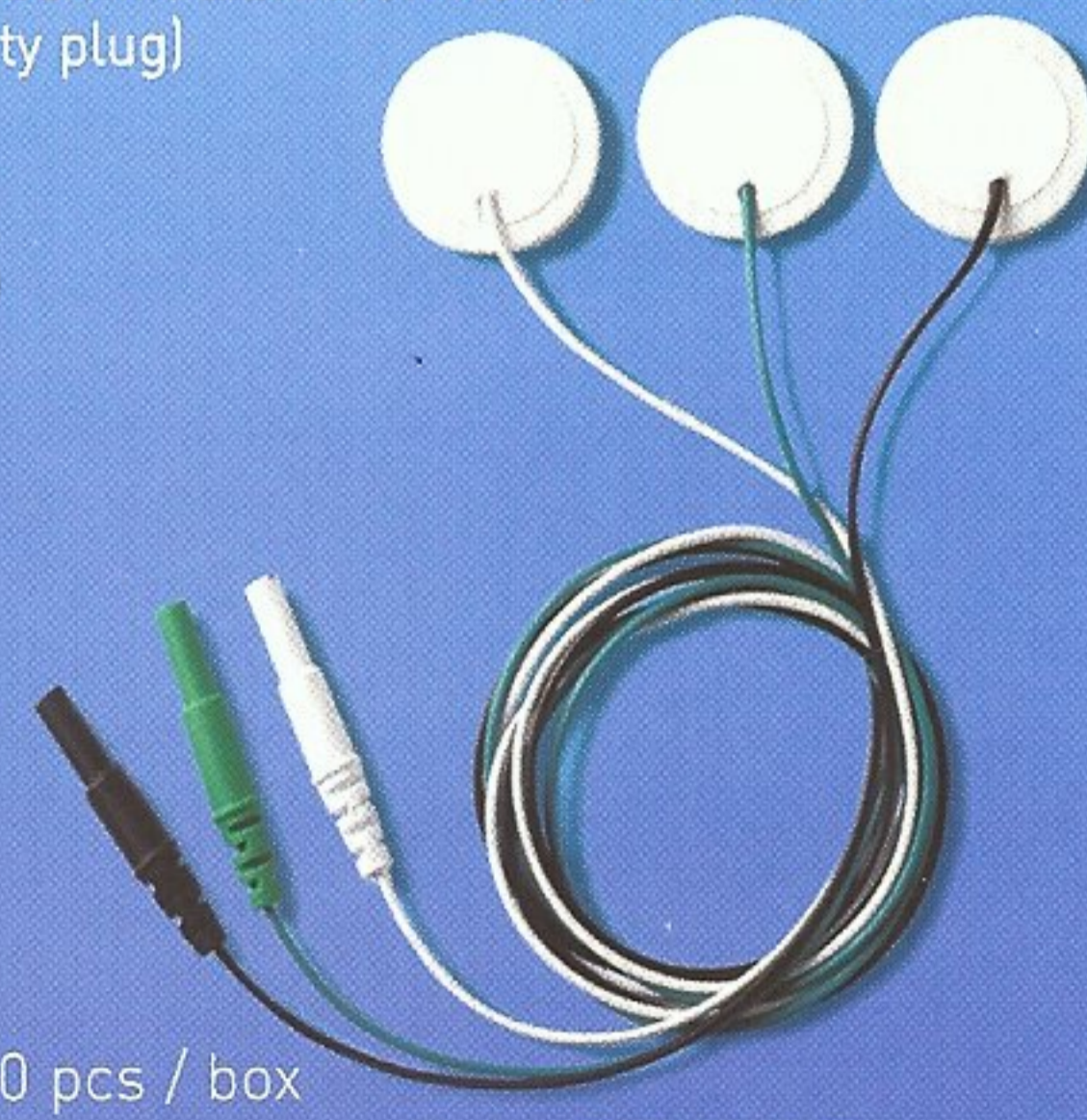
RT 22 LWS

22 mm.  
safety 1,55 mm

Foam

Solid

Carbon



3 pcs / pouch - 300 pcs / box

**Packaging**

3 pcs / pouch - 300 pcs / box

Available also with 22 mm diameter Model RT 22 LWF  
(with 4 mm female plug)

Available also with 30 mm diameter Model RT 30 LWS  
(with 1,55 mm safety plug)

# MEDI SENSOR LINE

## MONITORING & RESTING ECG'S

### MODEL F 50-S



Ø 50 mm.

**Dimensions**

Foam

**Backing**

Solid

**Gel**

Ag/AgCl

**Sensor**

30 pcs / pouch – 1200 pcs / carton

Available also with liquid gel Model F 50-L

### MODEL F 3642-S



Ø42.5 x 36.5 mm.

Foam

Solid

Ag/AgCl

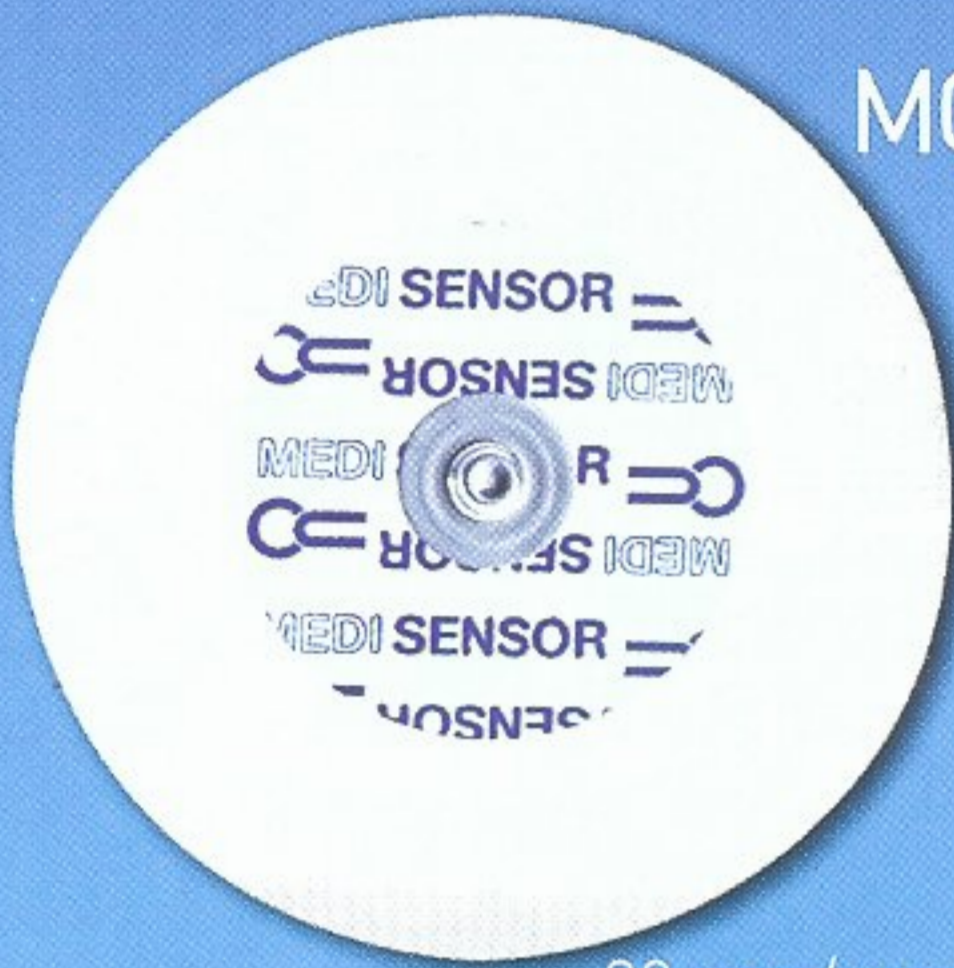
**Packaging**

50 pcs / pouch – 2000 pcs / carton

Available also with liquid gel Model F 3642-L

## HOLTER / LONG MONITORING

### MODEL W 601-S



Ø 55 mm.

**Dimensions**

TNT

**Backing**

Solid

**Gel**

Ag/AgCl

**Sensor**

30 pcs / pouch – 1500 pcs / carton

Available also with Ø 50 mm Model W 601  
and also with liquid gel Model W 601-L

### MODEL T 601-S



Ø 55 mm.

MICROPORE

Solid

Ag/AgCl

**Packaging**

30 pcs / pouch – 1500 pcs / carton

## STRESS TEST

### MODEL FS 50-L



Ø 50 mm.

**Dimensions**

Foam

**Backing**

Liquid

**Gel**

Ag/AgCl

**Sensor**

30 pcs / pouch – 1200 pcs / carton

### MODEL F 55-L



Ø 55 mm.

Foam

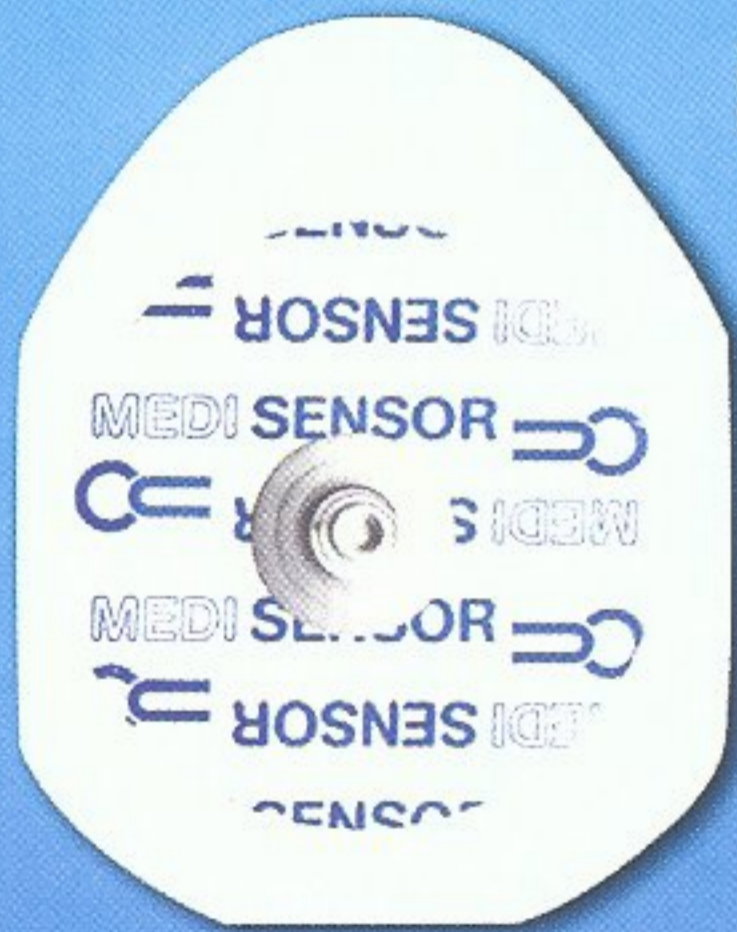
Liquid

Ag/AgCl

**Packaging**

30 pcs / pouch – 1200 pcs / carton

### MODEL FS 501-S



Ø 35x45 mm

**Dimensions**

Foam

**Backing**

Solid

**Gel**

Ag/AgCl

**Sensor**

50 pcs / pouch – 2000 pcs / carton

**Packaging**

## MULTIFUNCTION

### MODEL F 50-S BLUE



Ø 50 mm.

Foam

Solid

Carbon

30 pcs / pouch – 1200 pcs / carton

Ideal for all ECG monitoring, radiolucent application included!

## SUCTION CHEST ELECTRODES



Ag/AgCl sensor to guarantee maximum reliability in signal transmission • Suction cup made of a special /soft mixture to enhance the flexibility and therefore long duration over time.

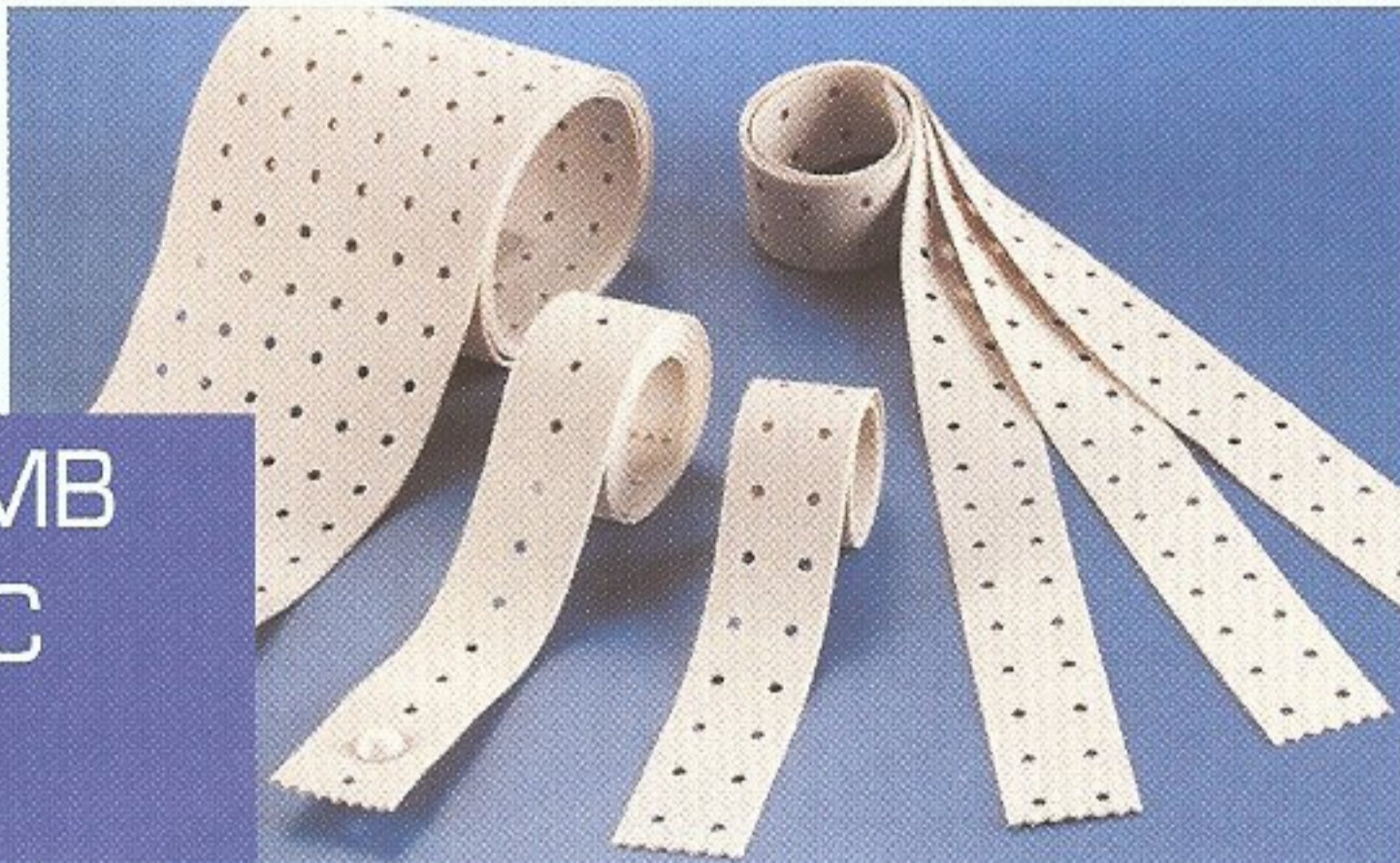
Available in three sizes: Ø15 mm for pediatric use / Ø 24 mm and Ø 30 mm for adult use.

## CLAMP ELECTRODES



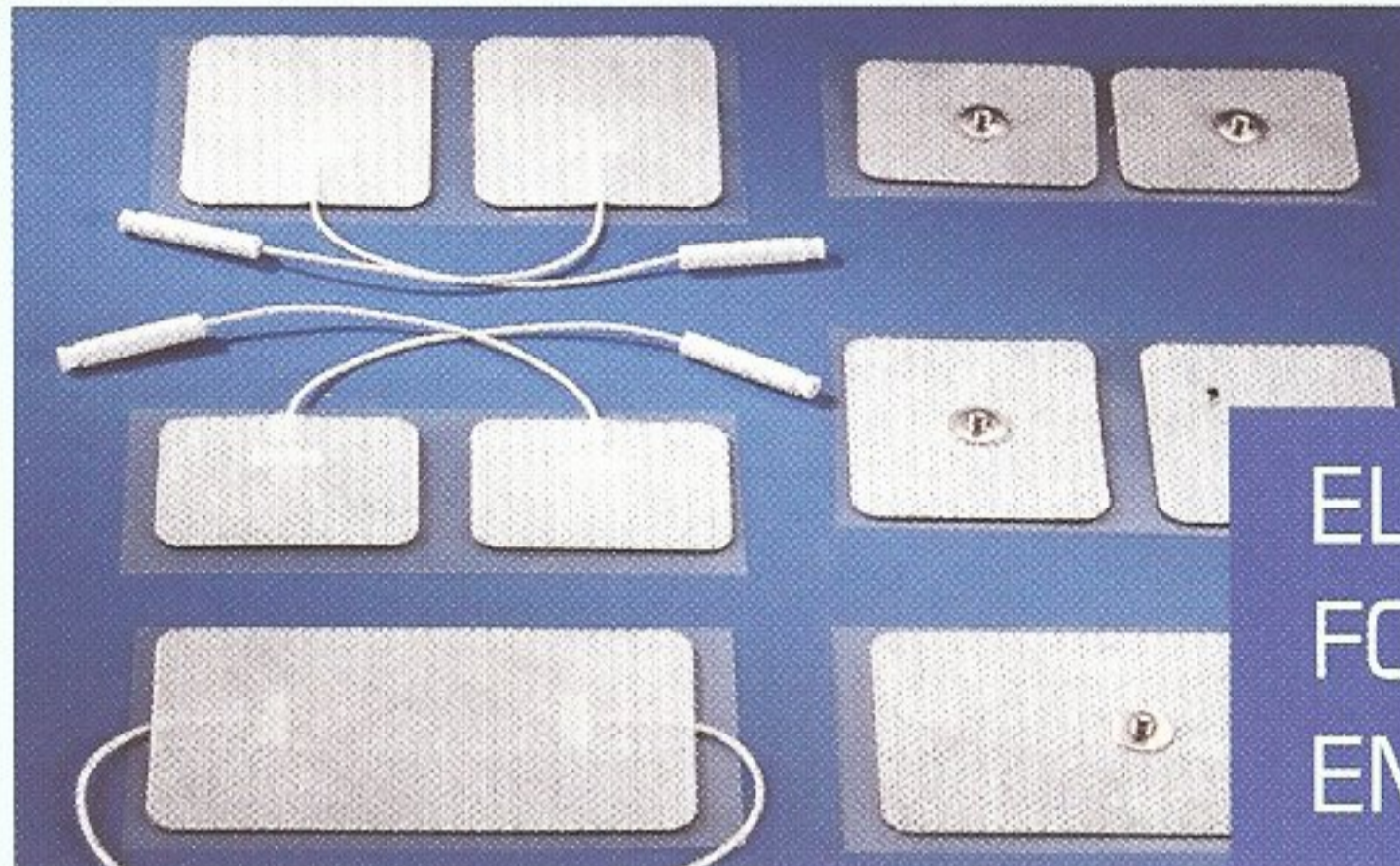
Classical-designed clamps with an improved quality. Ag/AgCl to ensure excellent signal transmission • Silver component to prevent distortions and to increase efficiency • Universal connection • Comply with AAMI standards • Available in yellow, green, red and black colours for adult and pediatric use.

## RUBBER LIMB & THORACIC STRAPS



For attaching electrodes • the special "anti-aging" treatment retards the crystallization of the rubber when exposed to the sun or air • available in different sizes: for limbs use - one hole (15 mm x 40 cm / 25 mm x 45 cm), - two holes (32mm x 45cm) - for thoracic use - one hole (32mm x 135cm), six holes (100mm x 135cm).

## ELECTRODES FOR TENS AND EMG



• Superior quality • available with a single or double helix • free terminal lead wires or with safety CAP • individual bags - package with 50 bags • manufactured in compliance with EN ISO 9001 and AAMI standards.

## ELECTRO SURGICAL PLATES



• Made of FOAM suitable to obtain perfect results with all instruments • manufactured and tested in compliance with EN 60601-1/EN 60601-2/AAMI-HF 18 • available with one zone and two zones and REM alarm for adults (adhesive surface 215 sq cm), for children (surface 129 sq cm) and for new born (surface 63 sq cm). **All the models are available even equipped with cables.**

## DEFIBRILLATION PADS



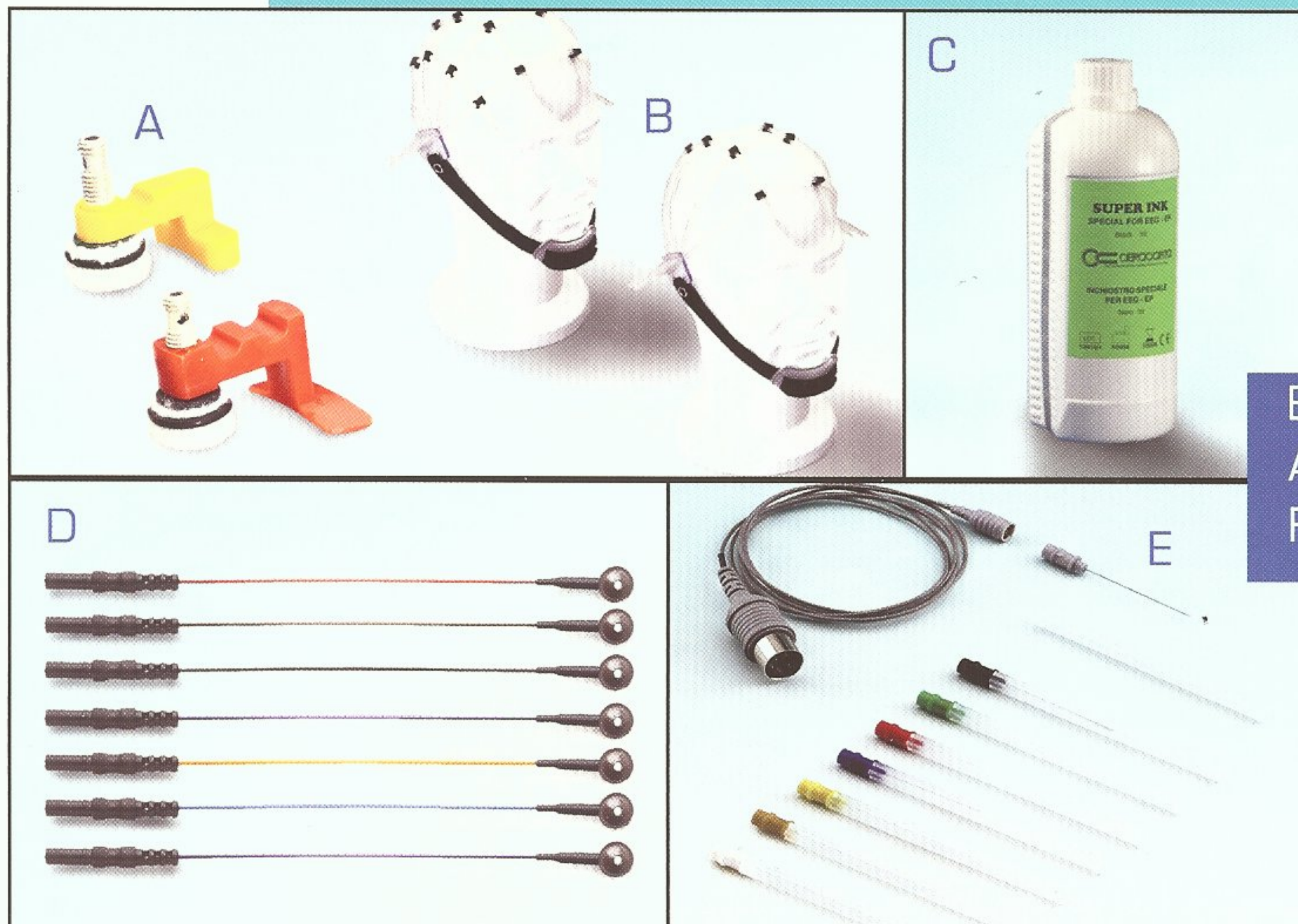
Produced using a high quality material • flexible foam • bio-compatible akrylic adhesive • conductive hydrogel • maintain a stable conductivity to temperature, humidity and time • avoid the direct contact between metal paddles and patient's skin • do not contaminate the metal paddles and do not corrupt future defibrillations • **packing: 2pads/bag - 50 pads/box.**

## PULSE OXIMETER SENSORS



A broad range of sensors to monitor and detect the arterial oxygen saturation. Excellent quality and proven accuracy are the characteristics that better describe a whole series of disposable and reusable sensors.

Suitable for all the main fittings spread on the market and perfectly matching with adults/children and newborn needs, these sensors do ensure the best performance and the top reliability.

ELECTRODES &  
ACCESSORIES  
FOR EEG & EMG

A serie of high quality/performing EEG-EP accessories enrich our range:

**A) BRIDGE ELECTRODES** Made of silver/silver chloride to optimize signal transmission. Available in three colours (red, blue, yellow)- Slightly curved support to improve head adaption. Three different types of connection (horizontal, vertical, with clamp electrode);

**B) SILICONE HEADCAPS** With 2 or 4 adjustable bands to fit for various requirements. Anatomically-designed earmuffs. Available in three sizes (Small-Medium-Large);

**C) SPECIAL INK FOR EEG** Suitable & excellent for all devices (Siemens excluded), allowing a perfect trace without blurs. Black colour- 1 litre bottle with graduated scale- (6 bottles per box- 4 boxes per carton);

**D) DISK ELECTRODES** Available in silver/silver chloride or gold - 10 mm diameter- With 120-150-200-250 cm lead wire & DIN 42802 safety plug - 10 electrodes per set with coloured lead wires (available 10 colours);

**E) DISPOSABLE CONCENTRIC NEEDLES FOR ELECTROMYOGRAPHY** Easy to use thanks to an ergonomic handgrip and an extremely sharp point - Recording area marker - Equipped with wings for automatic unfastening -Shielded, light & flexible lead wire with 5 pole DIN 45322 connector and entirely shielded handgrip. Available in different diameters (from 0.35 to 0.60 mm) and different lengths (from 20 to 70 mm) - 50 pcs per packing.

## MOUTHPIECES



Made of material particularly resistant to saliva or manipulation, perfectly hygienic, without residues and non-allergic • can be used on most spirometers of the most important brands present on the market • available in the external diameters 22-26-28-30 and 34 mm, but in the case of large orders the customer can request a specific diameter • boxes of 500 pieces • an extremely handy dispenser is available on customer's demand.



EC product compliance



COMPANY WITH QUALITY MANAGEMENT  
SYSTEM CERTIFIED BY DNV  
= ISO 9001:2008 =  
ISO 13485:2003

Via Secondo Casadei N.14  
zona industriale Villa Selva - 47122 Forlì (Italy) tel. +39.0543.780055 - fax +39.0543.781404  
www.ceracarta.it - e mail: export@ceracarta.it

## 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)

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



# 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**

