ORDIN DE PLATA NR.: 837	DATA EMITERII:20 iulie 2021
PLATITI: 4000-00	LEI: Patru Mii lei 00 bani
PLATITOR: (R) "BIOSIST MLD" S.R.L.	EM CONTUL DE PLATI/CODUL IBAN MD95ML000000002251429243 CODUL FISCAL :1010600028048 /
PRESTATORUL PLATITOR BC"Moldindconbank"S.A.	CODUL BANCII fil."Invest" Chisinau :MOLDMD2X329
	pen CONTUL DE PLATI/CODUL IBAN entral MD23TRPCCC518430B01859AA CODUL FISCAL :1016601000212 /
PRESTATORUL BENEFICIAR Ministerul Finantelor -	
DESTINATIA PLATII:/P102 arantia pentru oferta l hizi?ie publica nr. occ 02250808 din 24.07.2021	/4000,00 Pentru g: TIPUL TRANSFERULUI a procedura de ac: NORMAL/URGENT :N ls-b3wdp1-MD-16234:
	: L.S.
DATA PRIMIRII:2 DATA EXECUTARII:	: EMITENTULUI :
CONDUCATOR: Web Poiata V MIIGYwYJKoZIhvcNAQcCoI	<pre>fitalie IGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb</pre>
DQEHAaCCBGwwggRoMIIDUKA	.DAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq:
SIb3DQEBCwUAMCIxIDAeBgN	VBAMTF0NFUlQxLUNBLUlvbGRpbmRjb25iYW5rMB4:
	OMDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA: DwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml
DQEHAaCCBHAwggRsMIIDVKA SIb3DQEBCwUAMCIxIDAeBgN DTIxMDEyODExMzkxOFoXDTI	(semnatura electronica) chin Alexandr GWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3 .DAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG IVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X 0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw wYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv
L.S.	(semnatura electronica)
CONDUCATOR: CONTABIL-SEF:	(semnatura manuala)
SEMNATURA PRESTATORUL	(semnatura manuala)
MOTIVUL REFUZULUI	:: : L.S.



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

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

Fax: (373-22) 43-44-22 cod: MOLDMD2X329

Data 14. IAN. 2016 Nr. 03/2 - 19/23 Республика Молдова, MD-2068 мун. Кишинэу, бул. Московей, 14/1 Тел.: (373-22) 43-44-81, 43-46-24

Факс: (373-22) 43-44-22 код: MOLDMD2X329

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

1 Balney

Codul băncii MOLDMD2X329.

Director

Director financia

Nina Turcan

Nina Balmuş

Ex. Diana Brinza Tel. 43-45-96



# CERTIFICAT DE ÎNRECISTRARE

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

Numărul de identificare de stat - codul fiscal 1010600028048

Data înregistrării

Data eliberării

12.08.2010

12.08.2010

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul S. Sizes

MD 0101250





### I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

### **EXTRAS**

din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

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.

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,

Asociați:

- 1. POIATA VITALIE 33,40 %
- 2. NASEDCHIN ALEXANDR 33,30 %
- 3. KOJEVNIKOV DMITRII 33,30 %.

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: 28.04.2021.

Specialist coordonator tel. 022-207-840

Lazari Aliona



c/f 1010600028048; adresa: or. Chişinău, str. Albişoara 16/1 of.7 tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519. Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

# Lista fondatorilor Biosistem-mld SRL

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

### Дата предоставления 11.05.2021 10:00:47

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

### SITUAȚIILE FINANCIARE

Entitatea: <u>BIOSISTEM MLD S.R.L.</u>
Cod CUIÎO: <u>40717392</u>
Cod IDNO: <u>1010600028048</u>

Sediul:

MD:
Raionul(municipiul): 106, DDF RISCAN
Cod CUATM: 0150, SEC RISCAN
STCADUS SECTION SECTION

Activitatea principală: <u>Ga646. Comert cu ridicata al produselor farmaceutice</u>
Forma de proprietate: <u>16. Proprietate Colectivă</u>
Forma organizatorico-juridică: <u>530. Societăti cu răsoundere limitată</u>

Date de contact:
Telefon: ±37322809719
WEB:
E-mail: zmil3@mail.ru
Numele și coordonatele al contabilului-șef: Di (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 3 persoane. Persoanele responsabile de semnarea situațiilor financiare\* Nasedchin Alexandr

Unitatea de măsură: leu

BILANŢUL

			Sold la		
r. cpt.	Indicatori	Cod rd.	Începutul perioadei de gestiune	Sfîrşitul perioadei de gestiune	
1	2	3	4	5	
	ACTIV				
	ACTIVE IMOBILIZATE				
	I. Imobilizări necorporale				
	Imobilizări necorporale în curs de execuție	010			
	2. Imobilizări necorporale în exploatare, total	020	487		
	din care:				
	2.1. concesiuni, licențe și mărci	021	487		
	2.2. drepturi de autor și titluri de protecție	022			
	2.3. programe informatice	023			
	2.4. alte imobilizări necorporale	024			
	3. Fond comercial	030			
	Avansuri acordate pentru imobilizări necorporale	040			
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	487		
	II. Imobilizări corporale				
	Imobilizări corporale în curs de execuție	060			
	2. Terenuri	070			
	3. Mijloace fixe, total	080	2208593	279363	
	din care:				
	3.1. ciădiri	081			
	3.2. construcții speciale	082			
	3.3. maşini, utilaje şi instalaţii tehnice	083	2204135	279163	
	3.4. mijloace de transport	084			

	3.5. inventar și mobilier	085		
	3.6. alte mijloace fixe	086	4458	2000
A.	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120		
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2208593	2793637
	III. Investiții financiare pe termen lung			
	1. Investiții financiare pe termen lung în părți neafiliate	140		
	2. Investiții financiare pe termen lung în părți afiliate, total	150		
	din care:	151		
	2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
	2.2 împrumuturi acordate părților afiliate	152		
	2.3 împrumuturi acordate aferente intereselor de participare	153		
	2.4 alte investiții financiare	154		
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
	IV. Creanțe pe termen lung și alte active imobilizate			
	Creanțe comerciale pe termen lung	170		
	Creanțe ale părților afiliate pe termen lung	180		
	inclusiv: creanțe aferente intereselor de participare	181		
	Alte creanțe pe termen lung	190		
	Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	2209080	2793637
	ACTIVE CIRCULANTE			
	I. Stocuri			
	Nateriale si obiecte de mică valoare și scurtă durată	240	54051	51978
	Materiale şi obiecte de mica valdare şi scurta durata     Active biologice circulante	250	54051	219/0
		250		
	3. Producția în curs de execuție			
	4. Produse și mărfuri	270	5710647	7221203
	5. Avansuri acordate pentru stocuri	280		
	<b>Total stocuri</b> (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	5764698	7273181
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	4337729	3912218
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	166486	74631
	Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350	4	2
			1647908	5756117
В.	7. Alte active circulante	360	1047908	
В.	7. Alte active circulante  Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	360 370	6152127	9742968
В.	Total creanțe curente și alte active circulante			9742968
В.	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)			9742968
B.	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360) III. Investiții financiare curente	370		9742968
В.	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)  III. Investiții financiare curente  1. Investiții financiare curente în părți neafiliate	370 380 390		9742968
В.	Total creante curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360) III. Investiții financiare curente 1. Investiții financiare curente în pârți aefiliate 2. Investiții financiare curente în pârți affiliate, total din care:	370 380		9742968
В.	Total creante curente și alte active circulante (rd. 300 + rd. 310 + rd. 320 + rd. 330 + rd. 340 + rd. 350 + rd. 360)  III. Investiții financiare curente în părți neafiliate  2. investiții financiare curente în părți afiliate, total	370 380 390		9742968

	Total investiții financiare curente (rd.380 + rd.390)  IV. Numerar și documente bănești TOTAL ACTIVE (CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)  TOTAL ACTIVE (rd.200 + rd.400 + rd.410)  TOTAL ACTIVE (rd.230 + rd.420)  P A S I V  CAPITAL PROPRIU  1. Capital social și neinregistrat  1. Capital nevărsat  3. Capital nevărsat	400 410 420 430 440 450	8911899 20828724 23037804	3942 20951 23752
	IV. Numerar și documente bănești  TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 r rd.400 + rd.410)  TOTAL ACTIVE (rd.230 + rd.420)  P A S I V  CAPITAL PROPRIU  I. Capital social și neinregistrat  1. Capital social  2. Capital nevărsat	420	20828724 23037804	20958
	(rd.290 + rd.400 + rd.410) TOTAL ACTIVE (rd.230 + rd.420) P A S I V  CAPITAL PROPRIU  I. Capital social și neînregistrat  1. Capital social  2. Capital nevărsat	430	23037804	
: :	(rd.230 + rd.420)  PASIV  CAPITAL PROPRIU  I. Capital social și neinregistrat  1. Capital social  2. Capital nevărsat	440		2375
	P A S I V CAPITAL PROPRIU  1. Capital social și neinregistrat  1. Capital social  2. Capital nevărsat			
:	Capital social și neînregistrat     Capital social     Capital nevărsat			
:	Capital social și neînregistrat     Capital social     Capital nevărsat			
:	Capital social     Capital nevărsat			
		450	5400	
	3. Capital neînregistrat		(	(
		460	,	
	4. Capital retras	470	(	(
			)	)
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	
-	II. Prime de capital	500		
-	III. Rezerve			
-	1. Capital de rezervă	510		
L	2. Rezerve statutare	520		
-	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
Į.	IV. Profit (pierdere)			
Ŀ	Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	21021465	1208
	3. Profit net (pierdere netă) al perioadei de gestiune	570	х	797
	Profit utilizat al perioadei de gestiune	580	x	()
7	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	21021465	2006
,	V. Rezerve din reevaluare	600		
,	VI. Alte elemente de capital propriu	610		
7	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	21026865	2006
1	DATORII PE TERMEN LUNG			
	Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:	641		
-	2.1. împrumuturi din emisiunea de obligațiuni inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
-	2.2. alte împrumuturi pe termen lung	643		
	Datorii comerciale pe termen lung	650		
-	Datorii comerciale pe termen lung     Datorii față de părțile afiliate pe termen lung	660		
-	inclusiv: datorii aferente intereselor de participare	661		
-	5. Avansuri primite pe termen lung	670		
-	6. Venituri anticipate pe termen lung	680		
-	7. Alte datorii pe termen lung	690		
-	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
-	Credite bancare pe termen scurt	710		
-	İmprumuturi pe termen scurt, total	720		

	din care:	721		
	2.1. împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	1331928	3252667
E.	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	159545	188105
	6. Datorii față de personal	760	2913	50
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	434590	187676
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	81963	58541
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	2010939	3687039
	PROVIZIOANE			
	Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	840		
F.	3. Provizioane pentru impozite	850		
F.	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	23037804	23752565

### SITUAȚIA DE PROFIT ȘI PIERDERE

		Perioada de	gestiune
Indicatori	Cod rd.	precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	27319617	2596317
din care:			
venituri din vînzarea produselor și mărfurilor	011	26856566	25044350
venituri din prestarea serviciilor și executarea lucrărilor	012	463051	91881
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vînzări	016		
Costul vînzărilor, total	020	15672962	1518681
din care:			
valoarea contabilă a produselor și mărfurilor vîndute	021	15672962	1518681
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	11646655	1077636
Alte venituri din activitatea operațională	040	28586	24760
Cheltuieli de distribuire	050	16306	1974
Cheltuieli administrative	060	964136	125977
Alte cheltuieli din activitatea operațională	070	417394	64016
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10277405	910427

Profit net (pierdere netă) al perioadei de gestiune (rd.160 - d.170)	180	8902416	797483
Cheltuieli privind impozitul pe venit	170	1178993	105115
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	10081409	902599
Rezultatul din alte activități: profit (pierdere) (rd.110 + d.140)	150	-195996	-7828
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Cheltuieli cu active imobilizate și excepționale	130		
/enituri cu active imobilizate și excepționale	120		
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-195996	-7828
heltuieli aferente diferențelor de curs valutar și de sumă	105	686605	59752
heltuieli aferente ieşirii investițiilor financiare	104		
cheltuieli aferente ajustărilor de valoare privind investițiile înanciare pe termen lung și curente	103		
nclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli privind dobînzile	101		
fin care:			
Cheltuieli financiare, total	100	686605	5975
venituri aferente diferentelor de curs valutar si de sumă	099	490609	4936
înanciare pe termen lung și curente venituri din iesirea investitiilor financiare	098		
venituri aferente ajustărilor de valoare privind investițiile	097		
nclusiv: veniturile obtinute de la părțile afiliate	096		
venituri din alte investitii financiare pe termen lung	095		
nclusiv: veniturile obtinute de la părtile afiliate	094		230
venituri din dobînzi	093		256
venituri din interese de participare	092		
din care:	091		
/enituri financiare, total	090	490609	5192

### SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorári	Diminuări	Sold la sfirșitul perioadei de gestiune
1	2	3	4	5	6	7
	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	(	(	(	(
	3. Capital neînregistrat	030				
l.	4. Capital retras	040	(	(	(	(
	Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
	Rezerve					
	Capital de rezervă	080				
III.	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	Corecții ale rezultatelor anilor precedenți	120	х			

IV.	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130				
IV.	Profit net (pierdere netă) al perioadei de gestiune	140	х			
	4. Profit utilizat al perioadei de gestiune	150	x	(	(	(
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160				
V.	Rezerve din reevaluare	170				
VI.	Alte elemente de capital propriu	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 +	190				

### SITUAȚIA FLUXURILOR DE NUMERAR

Indicatori	Cod rd Perioa precedentă		de gestiune
indicatori			curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobînzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investiții			
Încasări din vînzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Версия для печати Сохранить

### Расписка 2

Респондент

Фискальный код: <u>1010600028048</u>, наименование: <u>BIOSISTEM MLD S.R.L.</u>

Предоставил отчёт: RSF1\_21

предоставил отчет: <u>KSF1\_21</u> На фискальный период: <u>A/2020</u> Дата предоставления: <u>11.05\_2021</u> Временная метка отчёта зарегистрированного в Информационной Системе НБС : <u>11.05\_2021</u> 12:26:31

National Bureau of Statistics (NBS) received the electronic version of the report, sent by you. The data provided is verified by NBS.

Версия для печати Сохранить

### Расписка

Респондент

Фискальный код: <u>1010600028048</u>, наименование: <u>BIOSISTEM MLD S.R.L.</u>

Оискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчёт: RSF1\_21
На фискальный период: A/2020
Дата предоставления: 11.05.2021
Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС: 11.05.2021 10:00:47

c/f 1010600028048; adresa: str. Albişoara 16/1 of.7, or. Chişinău tel.+373-22-808517, +373-22-808719, fax +373-22-808519. Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Către Grupul de lucru pentru evaluarea Procedurii de achiziție Nr. ocds-b3wdp1-MD-1623402250808 din 2 iul 2021, 9:11 - 24 iul 2021, 9:11 din cadrul CAPCS

### **Declarație**

Prin prezenta, SRL "Biosistem-mld", declara ca:

- Va instala şi instrui personalului beneficiarului cu privire la utilizarea echipamentelor livrate, organizate la sediul beneficiarului de către personalul autorizat al furnizorului.
- Termenul de garanție pentru echipamentul oferit nu este mai mic de 24-36 de luni de la data livrării/instalării acestuia.
- Perioada de reacție: jumătate de oră sau mai puțin la telefon și 24 ore sau mai puțin la locul beneficiarului în cazul apariției defecțiunilor tehnice.
- Va organiza inspecțiile planificate / întreținerea profilactică și calibrarea conform programului stabilit și mentenanța dispozitivului medical pe durata perioadei de garanție, efectuat de către un inginer calificat al ofertantului.
- Anul producerii echipamentului nu este mai vechi de anul 2020.
- Va înregistra în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale bunurile contractate pînă la momentul livrării acestora.
- Pînă la momentul livrării va prezenta numărul de înregistrare din Lista producătorilor, conform prevederilor HG 212/2018 privind gestionarea Echipamentelor Electrice si Electronice (EEE).





# **OUR VISION**



**AT ORASCOPTIC, WE ENVISION** every healthcare procedure in the world being performed with superior visualization under the best ergonomic conditions for the clinician to drive the best patient outcomes.

**Recognized as a pioneer** in medical vision for over 35 years, Orascoptic continues to offer healthcare professionals superior products that focus on magnification and illumination.

- Our legacy of advanced performance and clinician-first features sets the bar for craftsmanship, innovation and durability.
- Each Orascoptic loupe is custom-crafted with meticulous precision in Madison, Wisconsin and personalized to the individual's facial geometry, ensuring optimal resolution across the widest and deepest field of view.
- Engineered with performance and comfort in mind, our loupes employ
  rich details such as adjustable nose pads, flexible temple hinges, anti-reflective
  lens coatings and working distances refined in half-inch increments. Additionally,
  steep declination angles allow for improved posture and help reduce strain.

**Discover how Orascoptic continually shatters the status quo** with award-winning optical innovations such as the EyeZoom™ loupe with three adjustable magnification levels and the XV1™ loupe, the first and only all-in-one wireless loupe & headlight.

### **TABLE OF CONTENTS**

4 20
LOUPES LASER PROTECTION

13 21
FRAMES SAFETY PRODUCTS

15 22



# **LOUPES**

### HDL™ 2.5 MICRO

**Pushing the boundaries** of a typical micro optic, the loupe provides a generous field of view with edge-to-edge clarity. The exceptionally small profile also allows for additional viewing space above the telescope.

### HDL™ 2.5 MACRO

**Delivering an equivalent image quality** to the HDL 2.5 Micro, the HDL 2.5 Macro distinguishes itself with sizeable field width that allows instruments to be transitioned into the field of view with ease.

### **MOUNTING OPTIONS**

Through-the-Lens

### **FRAME OPTIONS**

ErgoEdge<sup>™</sup> · Flak 2.0<sup>®</sup> · Rydon<sup>™</sup> · Tempo<sup>™</sup> Victory<sup>™</sup> · XVI<sup>™</sup>

### **MOUNTING OPTIONS**

Through-the-Lens

### **FRAME OPTIONS**

ErgoEdge<sup>™</sup> · Flak 2.0<sup>®</sup> · Rydon<sup>™</sup> · Tempo<sup>™</sup> Victory<sup>™</sup> · XV1<sup>™</sup>





### **SPECIFICATIONS** Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*	
HDL Micro	2.5x	Customized to each user	3.4" (8.75 cm)	7.0" (17.80 cm)	TTL 1.36 oz (38.60 g)	
HDL Macro	2.5x	Customized to each user	4.0" (10.40 cm)	5.0" (12.70 cm)	TTL 1.80 oz (50.70 g)	

\* measured on Orascoptic Victory Frame, see pg 13



### **HDL™ 3.0**

Comparable to its predecessor — the HDL<sup>™</sup> 2.5 — this custom-crafted loupe boasts edge-to-edge clarity and a generous field of view.

Compact and lightweight, this loupe is designed to deliver a comfort rarely associated with Galilean optics of equivalent magnification power.

### **MOUNTING OPTIONS**

Through-the-Lens

### **FRAME OPTIONS**

ErgoEdge<sup>™</sup> · Flak  $2.0^{\circ}$  · Rydon<sup>™</sup> · Tempo<sup>™</sup> Victory<sup>™</sup> · XV1<sup>™</sup>



SPECIFICATIONS Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*	
HDL	3.0x	Customized to each user	3.1" (7.90 cm)	7.5" (19.0 cm)	TTL 1.70 oz (48.70 g)	

\* measured on Orascoptic Victory Frame, see pg 13



# **LOUPES**

### **HDL™ PRISMS**

**Prismatic Expanded Field Loupes** — Ranging from 3.5x to 5.5x, these loupes are designed for healthcare professionals who perform exacting procedures. The HDL prisms enable precise interactions, enhanced visibility and provide a customizable declination angle that accommodates various surgical procedures. The compact design and brushed metallic

finish of the telescope offers an aesthetically pleasing element to this medical device.

### **MOUNTING OPTIONS**

Through-the-Lens

### **FRAME OPTIONS**

ErgoEdge<sup>™</sup> · Rydon<sup>™</sup> · Tempo<sup>™</sup> · Victory<sup>™</sup> · XV1<sup>™</sup>

**SPECIFICATIONS** Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*
HDL 4	3.5x	Customized to each user	3.5" (8.90 cm)	3.6" (9.10 cm)	TTL 2.4 oz (67.5 g)
	4.5x	Customized to each user	2.95" (7.50 cm)	2.64" (6.70 cm)	TTL 2.5 oz (71.5 g)
	5.5x	Customized to each user	2.51" (6.40 cm)	2.32" (5.90 cm)	TTL 2.6 oz (74.4 g)

\* measured on Orascoptic Victory Frame, see pg 13

HDL 4.5

HDL 3.5

HDL 5.5





# LOUPES INTERCHANGEABLE MAGNIFICATION

### **OMNIOPTIC™**

### Discover the first and only interchangeable magnification loupe

that allows clinicians to select the optimal magnification power for each procedure. Accommodating four magnification powers ranging from

2.5x - 5.5x, the OmniOptic is an ideal system for users looking to increase their magnification

power over the course of their career.

### **MOUNTING OPTIONS**

Through-the-Lens

### **LOUPE OPTIONS**

HDL™ 2.5 Macro · HDL 3.5 · HDL 4.5 · HDL 5.5

### **FRAME OPTIONS**

ErgoEdge<sup>™</sup> · Rydon<sup>™</sup> · Tempo<sup>™</sup> Victory<sup>™</sup> · XV1<sup>™</sup>





**SPECIFICATIONS** Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Weight*
OmniOptic	2.5x	Customized to each user	2.02 oz (57.3 g)
	3.5x	Customized to each user	2.66 oz (75.3 g)
	4.5x	Customized to each user	2.79 oz (79.1 g)
	5.5x	Customized to each user	2.90 oz (82.1 g)

\* measured on Orascoptic Victory Frame, see pg 13



# **OPTICS** ADJUSTABLE MAGNIFICATION

### EYEZOOM™ & EYEZOOM™ MINI

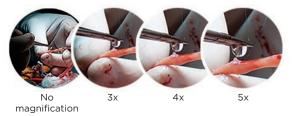
Offering two adjustable magnification solutions, EyeZoom™ features three magnification levels ranging from 3x-5x, while EyeZoom Mini™ features two magnification levels allowing the user to switch between 2.5x and 3.5x. Orascoptic's EyeZoom and EyeZoom Mini offer clinicians the ability to switch between multiple magnification powers to

accommodate a variety of procedures that require varying degrees of detail. Use lower magnification for routine dental examinations and preparation for crown and bridge procedures. Increase magnification for more complex and exacting procedures.



# EYEZOOM ADJUSTABLE MAGNIFICATION

EyeZoom employs 3-step variable magnification





# EYEZOOM MINI ADJUSTABLE MAGNIFICATION

EyeZoom Mini employs 2-step variable magnification



# **QUALITY ENGINEERING**

Optics co-engineered by Orascoptic™ & Konica Minolta™





A S C O A T

The first ever 3-in-1 and 2-in-1 adjustable magnification loupes, EyeZoom and EyeZoom Mini were developed to assist healthcare professionals view an operating site from multiple perspectives, conforming to fit each user's individual preference.

# MOUNTING OPTIONS Through-the-Lens FRAME OPTIONS ErgoEdge™ · Rydon™ · Tempo™ · Victory™ · XVI™ EyeZoom EyeZoom Mini

SPECIFICATIONS Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power Working Distance		Field Width	Field Depth	Weight*
EyeZoom	3.0x	Customized to each user	4.0" (10.20 cm)	4.0" (10.20 cm)	
	4.0x Customized to each use		3.25" (8.30 cm)	3.25" (8.30 cm)	TTL 3.4 oz (97.6 g)
	5.0x	Customized to each user	2.50" (6.35 cm)	2.50" (6.35 cm)	
EyeZoom Mini	2.5x	Customized to each user	3.97" (10.10 cm)	4.76" (12.10 cm)	TTI 2 C o= (77.7 c)
	3.5x	Customized to each user	3.19" (8.10 cm)	3.78" (9.60 cm)	TTL 2.6 oz (73.7 g)

<sup>\*</sup> EyeZoom measured on Orascoptic Legend Frame; EyeZoom Mini measured on Orascoptic Victory Frame, see pg 13



# **HYGIENE LOUPES**

### **RDH ELITE™**

Orascoptic's first loupe with a singular focus on the dental hygiene

**industry.** Designed by a team of both practicing hygienists and industry-recognized experts in ergonomics and infection control, the RDH Elite is centered on improving ergonomics and productivity.

### **MOUNTING OPTIONS**

Through-the-Lens

### **FRAME OPTIONS**

Iconic · Sport



**SPECIFICATIONS** Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width	Field Depth	Weight*	
RDH Elite	2.5x	Customized to each user	4.0" (10.20 cm)	6.0" (15.20 cm)	TTL 1.9 oz (58.4 g)	





### RDH ELITE EDGE™

**Ergonomic focus** — Accommodates steep telescope declination for proper posture.

**Optimal Field of View** — Encompasses a field width and depth recommended for dental hygiene professionals.

**Infection Protection** — Deep carrier lens and custom-designed side shields provide additional protection from debris and backsplash.

**Fashionable** — Iconic frame styles feature interchangeable temple tips and color emblems allowing you to add your own personal style.



RDH EliteEdge frame



**SPECIFICATIONS** Each loupe package includes side shields, head strap, personalized storage case, prescription lens, optical screw driver and cleaning cloth.

Series	Power	Working Distance	Field Width Field Depth		Weight*	
RDH EliteEdge	2.5x	Customized to each user	4.0" (10.20 cm)	6.0" (15.20 cm)	TTL 1.5 oz (43.3 g)	

\* measured on Orascoptic RDH Elite Edge Frame, see pg 13



# **FLIP-UP LOUPES**

### UNIVERSAL FLIP-UP™

**Flip-ups generally afford steep declination angles** up to 55 degrees. Our design features a vertical slide that allows advanced flexibility to position the telescopes in front of the pupils. They are assembled to the customer's PD at factory, but the horizontal PD bar allows the user to fine-tune

convergence. The "universal flip" feature allows the customer to transfer the telescopes to a variety of different eyewear. If worn on ophthalmic eyewear, the customer's prescription is updated every time they purchase a new pair of glasses.

### **MOUNTING OPTIONS**

Flip-up

### **LOUPE OPTIONS**

HDI™ 2.5 Macro

### **FRAME OPTIONS**

Titan

### **COMPATIBLE WITH ...**

Safety Glasses · Leaded Glasses (North America only)
Ophthalmic Glasses (your *own* eyewear!)

### **SPECIFICATIONS**

Field Weight	Field Depth	Weight
4.0" (10.40 cm)	5.0" (12.70 cm)	2.5 oz (70.9 g)





# FRAMES ICONIC

**TEMPO**<sup>TM</sup>



MATERIAL Stainless Steel · Aluminum

**MOUNTING OPTIONS** Through-the-Lens

**SIZES** Small · Medium · Large



Unlimited prescriptions



MATERIAL Titanium

**MOUNTING OPTIONS** Through-the-Lens

**SIZES** Small · Medium · Large



Unlimited prescriptions



# FRAMES SPORT

# RUDY PROJECT



### **ERGOEDGE™**



MATERIAL Nylon-blend branded Grilamid

**MOUNTING OPTIONS** Through-the-Lens

SIZES Small · Medium



Wide range of prescriptions, including bifocals

### **RYDON™**



MATERIAL Advance Carbon, Magnesium, Silicium, Grilamid, and Titanium

**MOUNTING OPTIONS** Through-the-Lens

SIZES One Size



Wide range of prescriptions, including bifocals

### **FLAK 2.0**<sup>®</sup>



MATERIAL Oakley® 0-Matter

MOUNTING OPTIONS Through-the-Lens

**SIZES** One Size



Black

Wide range of prescriptions, including bifocals

Oakley® and Flak 2.0® are registered trademarks of Oakley, Inc. Used with permission.



# **HEADLIGHTS**

Orascoptic was granted a U.S. patent for the optical design used in each of its headlights. This means we offer our customers a highly uniform spot with the least amount of weight in comparison to other

solutions on the market (see below). With Orascoptic-exclusive technology, clinicians can flood oral and surgical sites with a more uniform distribution of light, using an optical design that is lighter weight than before — that's a win-win!





### Each Orascoptic headlight model is tested

to ensure compliance with blue light testing standards set by the International Electrotechnical Commission. To learn more, visit orascoptic.com/products/headlights.







Manufacturer B



Manufacturer C



Manufacturer D

Based on results of independent third-party testing.



# HEADLIGHTS LOUPE & LIGHT

### XV1™

### Designed with a perfect synergy between magnification and

**illumination,** the XV1 is the **first and only** wireless loupe and headlight in one. Employing our lightest weight headlight, this frame has no exterior cabling and draws its power from battery packs in the temple tips. The counterbalanced design enhances overall comfort.









Steel



Black

Blue

Merlot

White



SPECIFICATIONS Each XVI includes power supply, charger, 4 rechargeable batteries, carrying case, 2 optical screwdrivers, cleaning cloth, curing filter.

Series	Weight	Light Intensity	Battery Life (4)	Charging Time
XV1	5.7 oz (161.7 g)	Low: 42 Lumens High: 68 Lumens	10 hrs on low 6 hrs on high	Less than 2 hours

All Orascoptic telescope models can be mounted on the XV1 frame.





# HEADLIGHTS CORDLESS

### **SPARK**<sup>TM</sup>

The self-contained cordless headlight that integrates with virtually any loupe or eyewear frame style. Featuring an innovative, patent-pending design, the Spark dispenses weight evenly across the bridge of a frame giving you a more comfortable fit with minimal concentrated facial pressure.

- Uniform Spot A precise focused light provides enhanced visibility during procedures.
- Versatile Power Charger A micro USB charger offers added convenience for charging on the go.
- Blue Light Compliant Maintains compliance with blue light testing standards for safety set by the International Electrotechnical Commission (IEC).
- Advanced Capacitive Touch Controls Power light on and off with ease in between procedures and patient consultations.



**SPECIFICATIONS** Each Spark package includes power supply, charger, 2 rechargeable batteries, carrying case, 2 optical screwdrivers, cleaning cloth, curing filter.

Series	Battery Type	Weight	Light Intensity	Battery Life (2)	Charging Time
Spark	Lithium-ion	1.12 oz (31.8 g)	32 Lumens	6 hours	2 hours



# **HEADLIGHTS**

### **ENDEAVOUR™**

Our second generation of the Endeavour headlight, this portable system provides a precise focused beam of light that distributes light evenly across the field of view. Convenient capacitive touch controls allow you to quickly adjust light settings without reaching into your jacket pocket.

- Uniform Spot The homogeneous round spot distributes light evenly across the field of view.
- Constant-Current Technology Brightness will not diminish during the run-time of the battery pack.
- Advanced Capacitive Touch Controls Quickly adjust light settings without having to reach into a coat or pants pocket.
- Multiple Light Levels Delivers 3 light intensity levels up to 68 lumens.
- Detachable Cable Lasting durability from Kevlar®-like fibers
- Battery Enclosure Durability from extruded aluminum



### **SPECIFICATIONS**

Series	Light Intensity	Intensity Control	Headlight Weight	Battery Type	Battery Weight	Battery Life	Charging Time
Endeavour	32/53/68 Lumens	Capacitive touch up to 68 Lumens	0.38 oz (10.8 g)	Lithium-ion	4.8 oz (138 g)	Up to 18 hours	Up to 3 hours



# **HEADLIGHTS**

### **ENDEAVOUR™ XL**

This patented headlight technology provides a precise beam of light that helps illuminate critical details that can often be overlooked by the naked eye. Utilizing constant-current technology, the headlight's light output will not diminish during the run-time of the battery pack.

- Increased Light Output Produces 25% brighter light output than the Orascoptic™ Endeavour™ headlight.
- Longer Run-Time Seize the day with up to 24 hours of battery life.
- Advanced Capacitive Touch Controls Quickly adjust light settings without having to reach into a coat or pants pocket.
- Multiple Light Levels Delivers a low, medium and high light intensity level up to 85 lumens.
- Detachable Cable Lasting durability from Kevlar®-like fibers
- Battery Enclosure Durability from extruded aluminum



### **SPECIFICATIONS**

Series	Light Intensity	Intensity Control	Headlight Weight	Battery Type	Battery Weight	Battery Life	Charging Time
Endeavour XL	53/68/85 Lumens	Capacitive touch up to 85 Lumens	0.38 oz (10.8 g)	Lithium-ion	7.3 oz (206 g)	Up to 24 hours	Up to 6 hours



# FRAMES BUILT FOR LOUPES

**Specializing in the design and manufacturing** of surgical loupes, dental loupes, and hygiene loupes for over 35 years, we have made it our mission to provide superior visualization to clinicians across the globe.

Key features of our award-winning, innovative loupes are highlighted below.





# **BUILD THE PERFECT LOUPE**

**Building your dream loupe is as easy as a few clicks.** Just let us know what loupe model you're interested in, and what frame style and color you want to mount it on, and you're on your way!

Our easy web interface will walk you right through every step in a matter of minutes.

orascoptic.com/loupe-builder





# LAB-TESTED RESOLUTION + BRIGHTNESS = CLARITY

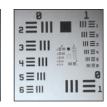
**The difference is striking.** In a series of third-party lab tests, Orascoptic's 2.5x loupes consistently outperformed the competition with superior combined scores for field width, field depth, resolution and light transmission. Most notably, our scores were outstanding in the areas that contribute most to image clarity.

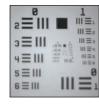
**Third-party testing confirms** that with best in class optical resolution and best in class light transmission, Orascoptic loupes deliver the clearest image quality in the industry.

THE RESOLUTION TEST Scores were determined by viewing the industry-standard USAF resolution target (below) through each telescope and performing the relevant calculations.

For the resolution test, Orascoptic's loupes measured: **125%** better than  $A \mid 12\%$  better than  $B \mid 26\%$  better than C







ORASCOPTIC (22.63 LP/mm)

Manufacturer A (10.03 LP/mm)

Manufacturer B (20.16 LP/mm)

Manufacturer C (17.96 LP/mm)

### THE LIGHT TRANSMISSION TEST

This test measured how much light passes through the optic to the eye. The greater the light transmission, the brighter the image which together enhances image clarity.

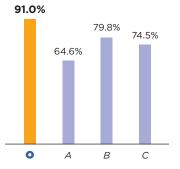
For the light transmission test, Orascoptic's loupes measured:

- 40% better than Manufacturer A
- 14% better than Manufacturer B
- 20% better than Manufacturer C

To learn more about the tests, visit *orascoptic.com*.

### Percentage of Light

Passing Through the Optics



### **Did You Know?**

As our eyes age, less light reaches our retinas. Orascoptic loupes have a greater light transmission which allows you to maintain a high level of clarity and detail as you progress in your career.















### **EC DECLARATION OF CONFORMITY**

DEC-960920-revC

This declaration of conformity is issued under the sole responsibility of the manufacturer

Manufacturer's	s Name:	Metrex Research, LLC dba Orascoptic				
Manufacturer's	s Address:	3225 Deming Way, Suite 190 Middleton, WI 53562 USA				
Authorized Rep	resentative within the Community:	Kerr Italia, Srl Via Passanti, 332 I-84018 Scafati (SA), Italy				
Device Classific	ation:	Class I				
Model:		Orascoptic Loupes				
Product Number	er(s):	Defined by Oracle Configurator, see CE technical file for details.				
Device Identific	cation:	000000-999999				
Application of (	Council Directive(s):	93/42/EEC as amended by 2007/47/EC 2011/65/EU				
Standard(s) to	which Conformity is Declared:	EN 50581:2012 EN 62321:2009 ISO 13485 ISO 14971				
The object of the declaration described above is in conformity with Directive 93/42/EEC concerning medical devices as amended by 2007/47/EC, and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.						
Date of Issue:	te of Issue: February 28, 2014					
Place of Issue: Metrex Research, LLC dba Orascoptic, Middleton, WI USA						
Jan 7 Onder		Cherard				
James Onderak, Dir	ector of I2E	James Chenard, Director of Quality				



# **Notary Cover Page For:**

## **ISO 13485 Certificate**

I certify that this is a true copy of the original ISO Certificate.

Drew Weightman, VP/GM Orascoptic Metrex Research LLC dba Orascoptic, Inc.	_ (Name(s) of individual(s))
This record was acknowledged before me on $3/25/3$	(Date)
State of: Wisconsin	
County of: Dane	
Signature of notary officer: <u>Ana Lynn H</u>	breid
Stamp/Seal:  NOTAR  NOTAR  OF WISCONSI	
My commission expires: 10-27-2024 (Date	te)





# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Metrex Research LLC

dba Surgical Acuity, Orascoptic

and Kerr Corporation

6650 Ronald Reagan Avenue

Madison Wisconsin 53704 USA

Holds Certificate No: FM 503651

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, packaging, distribution and repair of dental lights, magnification lenses, and electromechanical dental equipment.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Gary C Stade

Original Registration Date: 2005-12-12 Effective Date: 2020-11-17 Latest Revision Date: 2020-11-09 Expiry Date: 2023-11-16

Page: 1 of 1

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bsi.



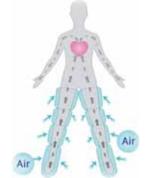
...making excellence a habit."

# AIR COMPRESSION THERAPY SOLUTIONS

All human body is supplied by peripheral circulation of blood and lymph.

Our systems help patients to recover from their disease by improving blood and lymph circulation and metabolism.

Our systems consist of air chambers and an air pump offering air compression massage to legs, arms or waist.



 28430 MAYLEA GIMA DIGITAL COMPRESSION MASSAGE with 2 legs (98x38 cm) - 4 chambers, 1 single and 1 double hose and 2 plastic feet guides

Skip function to choose directly the parts to be massaged. Fully digital management. Autocalibration functions. Manual: GB, FR, IT, ES. This system can operate with 3 compression modes (A, B, C).

MODE A MODE B MODE C

### **TECHNICAL SPECIFICATIONS**

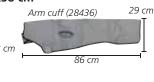
- pressure sensor
- digital timer (10, 20, 30, 40 min)
- digital pressure gauge (10~180 mmHg) • 28435 LEG 93x32 cm
- 28434 LEG EXTENSION ZIPPER 10 cm extra extension

• 28440 DOUBLE HOSE - to use two leg cuffs at the same time - spare

• 28436 ARM CUFF unique size - 86x29 cm

• 28437 WAIST CUFF 130x38 cm





- one touch connection hose plug

(28437)

- body size: 190x250x210 mm

- body weight: 3 kg

### • 28441 MK400L PROFESSIONAL COMPRESSION SYSTEM with 2 legs (XL), and 2 single hoses

MK400L is a professional air compression therapy system with essential functions for different kinds of patients. This system provides 3 compression modes (wave, squeezing, double squeezing), reverse compression settings, skip functions to select directly part to be pressurized and compression speed controller. Touch key pad display. Manual: GB, IT, ES.

### TECHNICAL SPECIFICATIONS Pressure range: 10~200 mmHg Use time: 1~90 minutes Automatic pressure detection - Body size: 415x310x160 mm Operating voltage: 220-240 V, 50/60 Hz, 50 VA - Body weight: 6.5 kg 28447 You can use 2 cuffs at the same time, MK400 has 2 connection plugs 28446

6 chamber legs

### Medical indications

- DVT (Deep Vein Thrombosis)
- Lymph edema
- Post-paralytic
- Limb convulsion
- Venosclerosis
- Chronic venous insufficiency (CVI)
- Post-mastectomy
- Post-trauma
- Spinal cord injury
- Varicose veins
- Sciatica
- Sprains
- Diabetes
- Arterial insufficiency

### Home care indications

- Lymph edema
- Diseases caused by interrupted blood circulation
- Cellulitis fat dissolution
- Pregnant woman's limb treatment
- Benumbed feet or hands
- Cold feet or hands
- Settlement of stress
- Exercise effects
- Insomnia
- Healthier body and elastic skin
- Old age, weakness and fatigue



• 28442 LEG CUFF L - 6 CHAMBERS - spare

• 28443 LEG CUFF XL - 6 CHAMBERS - spare

connections

- 28444 LEG EXTENSION ZIPPER XL 10 cm extra extension for 28443
- 28445 SINGLE HOSE spare
- 28446 ARM CUFF 6 CHAMBERS universal
- 28447 WAIST CUFF 6 CHAMBERS min-max girth 94-125 cm

A mode (Wave)

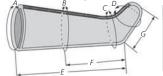
> The selected air chamber inflates and deflates by one chamber sequentially from foot up to thigh.

### B mode (Squeezing)

After all the selected air chambers inflate sequentially from foot up to thigh the inflated chambers deflate at once.

### C mode (B mode two times + Reverse A mode 1 time)

The selected air chambers inflate and deflate by two chambers sequentially from foot up to thigh. **Reverse setting:** it allows to change automatically the selected mode to reverse mode.



Cuff	Leg dimension (cm)								
Size	Α	В	С	D	E	F	G		
L	64,0	49,5	40,5	34,5	75,0	38,0	28,0		
XL	73,5	55,0	42,0	35,5	85,0	43,0	31,0		

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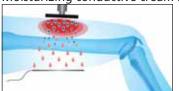
28364

# CR200 - PROFESSIONAL TECAR THERAPY

#### • 28364 CR200 TECAR THERAPY

Diathermy, also known as TECAR Therapy (meaning Capacitive and Resistive Energy Transfer), is a therapy stimulating the physiological healing process by accelerating the recovery time of motor function. Diathermy stimulates tissues endogenous heat production through the interaction of electromagnetic field and tissue. The heat is increased in a uniform controlled way. The electromagnetic interaction results in a ionic flow and consequently increases blood flow in the treated area. This process stimulates endogenous substances release (in particular cortisol and endorphins) that are necessary to reduce inflammations, pain and edemas. The new CR200 resistive/ capacitive diathermy is a modern and highly performing device easy to use by professionals. Preset programmes help use the device from the start. Moreover the device can set parameters (power, time therapy, capacitive/resistive modes) according to therapeutic needs. It allows the memorization of customized programmes. In this way patient protocols are easily consulted by therapists at any time. Equipped with a wide graphic display showing therapy parameters and different working modes. Selectable software language (GB, FR, IT, ES).

#### 33251 TECARTHERAPY CONDUCTIVE CREAM 1 I Moisturizing conductive cream ideal for Tecar therapy.



#### Capacitive mode

Electrode coated with ceramic material (mobile) and return plate (fixed). Indicated especially for soft tissues (muscle mass and lymphatic/vascular system). Benefits: specific intervention: easy control of the treated area.

Non isolated electrode (mobile) and return plate (fixed). Indicated especially for tissues with greater resistance (bones, joints, tendons, ligaments, cartilages). Benefits: high level of diathermy; chronic

#### STANDARD ACCESSORIES

- 1 multi-function probe for capacitive and resistive mode 2 electrodes Ø 35 mm (1 resistive + 1 capacitive) with 9.61 cm $^2$  effective working area 2 electrodes Ø 60 mm (1 resistive + 1 capacitive) with 28.26 cm $^2$  effective working area
- 1 integrated support for probe Bottle of conductive cream 1 kg User Manual: GB, IT, ES, FR

1 steel plate Power supply cable

# Resistive mode

diseases with fibrosis and degeneration

#### **TECHNICAL SPECIFICATIONS**

sprain

0

MAIN TREATMENTS

Capacitive

Resistive electrodes

knee arthrosis, arthrosynovitis, bursitis, cervicalgia, patellar chondropathy,

bruises, coxarthrosis, sprain, articular

pain, oedema, epicondylitis, epitro-chleitis, spinal disk hernia, plantar fa-sciitis, gonarthrosis, ACL, lymphedema,

back pain, meniscopathy, neuropathy,

periarthritis, muscle sprain, acute

tendinitis, chronic tendinitis

Skeletal-muscle pathologies

24 REHAB PROGRAMMES

Chondropathy

lectrodes

Power supply: 100-240 V, 50/60 Hz Max power consumption: 300 W (50 ohm load) Carrier frequency: 485 kHz Adjusta

Touch screen graphic display 7

Adjustable power: 0-100% Preset programmes, free memories

Lumbalgy, pubalgy and acute/chronic

Muscle contractures, bruise, muscle stretching, sprain, haematomas, tendon injury, superficial massage, deep

massage, muscle recovery, muscle

Osteoarticular pathologies

10 SPORT PROGRAMMES

Multifunction

Steel return

plate

# I-TECH LA 500 LASER THERAPY

#### • 28410 I-TECH LA 500 LASER THERAPY

Laser therapy device equipped with a new probe with an emitting diode that allows beam laser application directly to the treatment area.

I-TECH LA 500 is able to stimulate deep tissues by promoting a rapid cellular regeneration thanks to 500 mW power output and 810 nm wavelength. Professional user can adjust power output, therapy time and operation mode (continuous or pulse).

I-TECH LA 500 guarantees a fast intervention for the treatment of inflammatory and degenerative pathologies in orthopedic, neurologic and dermatologic area.

Thanks to its high performance healing time is significantly reduced. Supplied with probe, belts for probe fastening and safety glasses.

Manual in: GB, IT, FR, ES.

#### LASER THERAPY

The laser therapy uses the effects of energy produced by the light source penetration into the tissues.

Biochemical reactions are activated across the cellular membrane.

It has been observed that right doses of Laser light can stimulate cellular functions, in particular into the cells damaged by functional deficits. The main effects of Laser therapy are:

- improved blood flow: capillary and artery vasodilatation that results in local
- biostimulation: accelerated tissues repair, stimulation of protein synthesis, ADP production, electrolyte changes in the intra- and extra-cellular fluids and mitosis of fibroblasts, increase of collagen and elastin
- anti-inflammatory effect
- anti-oedema effect: lymphatic drainage stimulation
- analgesic effect



#### **TECHNICAL SPECIFICATIONS**

Power supply: 230 V, 50-60 Hz, ±10% Maximum laser output: 500 mW ± 20% Adjustable laser power output: 0%-100% Laser diode wavelength: 810 nm Beam divergence angle: 260 mrad Continuous output emission Fixed emission frequency

Fixed width duration Continuous or pulse mode of operation Pointing red light Diode probe (with reserved connection)

Adjustable therapy time: 0-30 minutes Diameter of laser beam: <10 mm Dimensions: 300x150x120 mm

#### **MAIN TREATMENTS**

- Polyarthritis Epicondylitis/Epitrochleitis Knee pain Myositis
- Oedema Sciatalgy/Lumbago Articular sprains Chronic Tenosynovitis -Muscle strains - Overcharge pathologies - Ecchymosis - Bursitis - Degenerative arthritis - Adhesive capsulitis - Arthrosis pains - Post-traumatic disorders
- Scars Rheumatic diseases

I-TECH UT2 - PROFESSIONAL ULTRASOUND THERAPY



#### **APPLICATIONS**

Tendinitis - Bursitis/Capsulitis - Hematomas and tissue reconstruction -Muscle contractures/Cramps - Neuralgias - Periarthritis - Cervicalgias Sciatalgy/Lumbalgy - Carpal tunnel syndrome - Epicondylitis/epitrochleitis -Contusions/sprains - Chondropathy - Massage - Arms/abdomen/legs/gluteus cavitation - Acne

#### **STANDARD ACCESSORIES**

1 handle with 5 cm<sup>2</sup> probe 1 handle with 1 cm<sup>2</sup> probe

1 power supply cable

- 1 power supply 15 V, 3 A 1 ultrasound gel User manual: GB, IT, ES, FR

# • 28358 I-TECH UT2 ULTRASOUND THERAPY - 2 probes

Professional ultrasound device equipped with 2 handles respectively with 5 cm<sup>2</sup> and 1 cm<sup>2</sup> probe. Its equipment and parameters setting allow high performance suitable for professional users.

It is provided with 10 preset programmes within which professional user can adjust following parameters:

- Frequency (1 or 3 MHz)
- Effective intensity (up to 3 W/cm<sup>2</sup>)
- Duty cycle (10% ÷ 100% stepping 10)
- Therapy time (up to 30 minutes)

#### **TECHNICAL SPECIFICATIONS**

Operating voltage: 100-240 V, 47/63 Hz, 1.35A, output 15V 3A max

Ultrasound frequency: 1 MHz ± 10% and 3 MHz ±10%

Output power: 0.5-10 W ± 20% when duty cycle ≥ 80% for 5 cm<sup>2</sup> ultrasound head 0.5-15 W  $\pm 20\%$  when duty cycle  $\leq 70\%$  for 5 cm<sup>2</sup> ultrasound head 0.1-2 W  $\pm 20\%$  when duty cycle  $\geq 80\%$  for 1 cm<sup>2</sup> ultrasound head

0.1-3 W ±20% when duty cycle ≤ 70% for 1 cm<sup>2</sup> ultrasound head

Max Power:  $3 \text{ W/cm}^2 \pm 20\% (1 \text{ MHz})$ ;  $3 \text{ W/cm}^2 \pm 20\% (3 \text{ MHz})$ 

Working frequency: 100 Hz

Duty cycle: 10%-100% stepping 10%

Maximum adjustable therapy time 30 minutes

Effective radiating area 5 cm<sup>2</sup> ± 20%; 1 cm<sup>2</sup> ±20%

Collimated beam type Ultrasound head (material) aluminium Direct contact and water immersion use

Led indicator Size: 350x186x86 mm

# GIMA UT AUTOMATIC: ULTRASOUND THERAPY UNIT



#### TECHNICAL SPECIFICATIONS

Treatment time: programmable from 1 to 30 minutes Selectable pulse/time%: 10%-20%-30%-50%-100% Pulse frequency: 2 pulses/second Max. intensity: 3 W/cm<sup>2</sup> Operating voltage: 115/230 V - 50/60 Hz - switchable

Electrical safety class I BF - Norms: EN 60601, EN 60601-2-5

#### • 28310 GIMA UT AUTOMATIC ultrasound therapy unit without head





Automatic system for ultrasound therapy which can use ultrasound head with oscillation frequency from 1 MHz to 3 MHz. Pulse frequency is 2 pulses/second. Modulation degree is selectable from 10% to 100%, through a digital keyboard. It is provided with digital adjustment of intensity with numeric

indication. Maximum output power is: 37.7 W (3 W/cm<sup>2</sup>). Luminous read-out for distributed power. Gima UT is recommended for: ultrasound lipoclasia, sports

medicine, arthritis, arthrosis, neuralgia and backpain. Supplied with power cord and user's manual. Made in Italy.

- 28312 1 MHz ULTRASOUND HEAD Ø 60 mm
- 1 MHz frequency is recommended for physiotherapy.
- 28313 3 MHz ÚLTRASOUND HEAD Ø 60 mm
- 3 MHz frequency is recommended for aesthetics.

# GIMA UTC 2: COMBINED ULTRASOUND AND ELECTROTHERAPY UNIT

#### • 28301 GIMA UTC 2 AUTOMATIC

UTC 2 is a programmable driver unit for ultrasound transducers with working frequencies from 1 up to 3 MHz together with 2 channels of electrotherapeutic current. UTC 2 delivers continuous or modulated ultrasound with programmable intensity and delivery time, suitable for thermo therapeutic deep treatment of different pathologic conditions. UTC 2 transducer handpieces can be used under water. UTC 2 delivers Dyadinamic, Faradic, Galvanic, Impulsive, T.E.N.S. and Bipolar electrotherapeutical currents.

- high brightness graphic touchscreen display
- intuitive icons interface
- controls of unit by multifunction knob, keys or touchscreen
- possibility to upgrade
- wide range of preset protocols
- customized programmes
- multi frequency handpieces
- automatic identification of the connected accessory
- continuous or pulsed delivery
- combined with electrotherapy
- sequence of treatment phases planning for each channel
- independent channels
- safety control blocks the output current in case of accidental disconnection of electrodes.
- 6 language software: GB, FR, IT, ES, DE, PT. Made in Italy.
   28302 1-3 MHz ULTRASOUND HEAD Ø 15 mm
- 28303 CONNECTING CABLE for electrotherapy spare
- 28304 CLIP RUBBER ELECTRODES 120x80 mm box of 12 • 28305 CLIP RUBBER ELECTRODES 45x60 mm - box of 12
- 28323 VELCRO ELASTIC BAND 100x8 cm spare

# GIMA 28301





#### **TECHNICAL SPECIFICATIONS**

Output frequency (MHz): 1.0 to 3.0 Max intensity (W/cmq): 3.0 ET channels: 2 Electrical input power (VA): 70

Max output direct current (mA): 30 Max output pulse current (mA): 70 Max output voltage (Vdc): 100 Power supply (Vac/Hz): 90-240 / 50-60

#### STANDARD ACCESSORIES

1-3 MHz ultrasound head Ø 35 mm

Connecting cable for electrotherapy 1-2 (28303)

4 rubber electrodes 120x80 mm; 4 rubber electrodes 45x60 mm

3 velcro elastic belt: 8x40, 8x60, 8x100 cm Power cable 2 m

-TECH

I-TEGA

# T-ONE COACH AND T-ONE MEDI SPORT - 4 CHANNELS ELECTROTHERAPY

Size: 150x90x35 mm

#### • 28401 T-ONE COACH ELECTROTHERAPY - 4 channels

A high performant muscle stimulator designed to improve your physical activity. Thanks to easy to use programs, it represents the ideal device for not professional athletes and for sports lovers in general. It is not only a muscle stimulator equipment. It is supplied by TENS protocols for pain relief and injuries recovery.

• 28402 T-ONE MEDISPORT ELECTROTHERAPY - 4 channels Professional equipment specifically designed for sport specialist users. Thanks to its muscle stimulation specialized programs it improves the sport performance. It is not only intended to increase your strength, it helps the recovery of sport injuries with specific treatment protocols.

#### Main features

- constant current generator (can guarantee a constant current even when skin condition changes, the device automatically stops in the event of accidental electrodes disconnection)
- four independent channels unit (up to 8 connectable electrodes)
- compensated biphasic square wave: current quantity from positive pole to negative one is constant to avoid polarization effect;
- monophasic wave generator (only for iontophoresis programs)
- 2+2 users programs
- backlight graphic colour display
- user feedback: the device recognizes patient connection
- soft-touch easy to use keyboard
- on-line 5 languages guide (GB, FR, IT, ES, DE) on display for fast instructions
- 4,8 V rechargeable battery pack

- 28401 - personalized programs for man and woman
  - maximum intensity 240 mApp, with 1 mA step regulation
  - 28351 PRE GELLED ELECTRODES 40x40 cm with cable box of 4

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I-TECH

28402

- 28373 PRE GELLED ELECTRODES 45x80 cm with cable box of 4
- 28381 IONOPHORESIS KIT spare

(1 elastic band, 2 silicone conductive electrodes, 2 sponges)

#### STANDARD ACCESSORIES

4 connection cables (8 connectable electrodes)

Kit of pre-gelled self-adhesive electrodes (square, rectangular, round) Ionophoresis kit: elastic belt, 2 silicone electrodes, 2 sponges, carrying bag (28402 only) Internal Ni-Mh rechargeable battery pack and battery charger

Electrode position manual and user manual (GB, FR, IT, ES). On request DE

BEAUTY	REHA	TENS	NEMS	MEM	2+2
18 programmes 28401 and 28402	10 programmes only 28402	16 programmes 28401 and 28402	14 programmes 28401 and 28402	Only 28402	28401 and 28402
Firming up Toning up Definition Modelling Microlifting Lipolysis abdomen Lipolysis thighs Lipolysis glutei and hips Lipolysis arms Tissue elasticity Capillarization Heaviness in legs Face Microlifting Handy Trode Breast Microlifting Handy Trode Décolleté Microlifting Handy Trode Face Wrinkles Handy Trode Face Wrinkles Handy Trode Collagen	Ionophoresis L Ionophoresis M Ionophoresis M MENS microcurrent Haematomas Oedema Tens sequential Tens Burst Atrophy prevention Atrophy	Tens rapid Tens endorphinic Tens max values Inflammatory Neck pain Backache/Sciatic pain Sprains/Bruises Vascularization Muscle relaxant Hand and wrist pain Plantar stimulation Epicondylitis Epitroclea Periarthritis Tens Burst Microcurrent	Warming up Resistance Resistance strength Basic strength Fast strength Explosive strength Deep capillarization Muscle recovery Agonist/Antagonist Sequential tonic contractions Sequential phasic contractions Muscle relaxant	Tens mem 1 Tens mem 2 Tens mem 3 Tens mem 4 Tens mem 5 NEMS mem 1 NEMS mem 2 NEMS mem 3 NEMS mem 4 NEMS mem 5 NEMS alternated NEMS alternated Battery test	Tens rapid Tens endorphinic Firming up Toning up Definition Modelling Microlifting Muscle relaxant Massage Capillarization Only 28402 Inflammatory Resistance, Resistance strength Basic strength, Fast strength Explosive strength, Hypertrophy Face Microlifting Handy Trode Décolleté Microlifting Handy Trode Décolleté Microlifting Handy Trode Face Wrinkles Handy Trode Forehead Wrinkles Handy Trode

## MIO-SONIC ULTRASOUND THERAPY DEVICE - 9 PROGRAMS • 28309 MIO-SONIC ULTRASOUND THERAPY

28309

Adhesions

Brachialgy

Capsulitis

Bursitis

Algodystrophy

Stretch marks

**Epycondilitis** 

Lymphedema

Innovative and high performance device both for home use and professional use. It combines compactness and high performances in a small, light and easy to use applicator. The lightness and handiness allows a continuous use without any difficulty.

Mio Sonic can be used for the following applications:

- pain therapy;
- sport injuries;
- aesthetic treatments.

Supplied with gel bottle, carrying and storage bag, medical power supply and multilanguage manual:

GB, FR, IT, ES. On request DE.

Osteoporosis Arthritis Neuralgias Cervicalgias Sciatalgy Sprains Cruralgy Wrinkles

Periarthritis Tendinitis Pubalgy Tallonitis Contusions Chondropathy Microlifting Epitrochleitis

#### **TECHNICAL SPECIFICATIONS** 9 programs;

1 MHz ultrasound, maximum output power 6.4 W, maximum intensity 1.6 W/cm<sup>2</sup>;

Collimated ultrasound beam for an optimal penetration beam; 3 ultrasound beam intensity levels 0,08 W/cm2 (low) - 0,8 W/cm2 (medium) -1,6 W/cm<sup>2</sup> (high);

Medical power supply; Direct contact device (not suitable for water immersion)

Size-weight: 200x47x69 mm - 190 g

**TREATMENTS** Muscular contractures Cramps Massage Drainage

Modelling Carpal Tunnel Oedema Venous stagnation Arms cavitation Abdomen cavitation Limb cavitation Gluteus cavitation Lumbalgy Hematoma Acne **Phonophoresis** 



# ORTHOMAG LOW FREQUENCY MAGNETOTHERAPY - 2 PROGRAMMES

 Biostimulation Pain management

28298

28296

28300

• 28298 ORTHOMAG low frequency magnetotherapy kit A professional low frequency magnetotherapy (PEMF) device that can be used everywhere. Lightweight, comfortable and flexible, fitting your body shape. Battery powered for dynamic use or power socket for use at home or in the office. Orthomag includes 2 programmes (75 Hz and 50 Hz) indicated for bone tissue pathologies,

joint diseases and pain management. Up to 25 Gauss per programme. Supplied with rechargeable lithium battery 3.7 V 900 mAh, wall mount charger (cable 1.5 m), universal flexible applicator (cable 1.5 m), test emission magnet, 2 elastic bands (S and L), carrying bag, manual (GB, FR, IT, ES). On request DE



Muscle pain

Anti-inflammatory



28296

Elastic

therapeutic

# MAG 700 LOW FREQUENCY, HIGH INTENSITY MAGNETOTHERAPY

**€** 0476

• 28296 MAG 700 MAGNETOTHERAPY - 1 channel New portable magnetotherapy ideal for home therapy. MAG 700 offers a high level of professional performances and it's indicated for several pathologies.

It allows comfortable home therapy through its basic accessories. MAG 700 has 7 pre-setted programmes for the treatment of several pathologies, 3 programmes identified by the working frequency (from

5 to 20 Hertz) and an Autoscan programme with continuous frequency variation for the treatment of both hard and soft tissues at the same time.

Possibility to adjust the magnetic field intensity for all programmes up to 70 Gauss.

Working frequencies are between 5 and 100 Hertz. Supplied with elastic therapeutic belt with 2 solenoids, power supply, carrying bag and manual (GB, FR, IT, ES).

11 PROGRAMMES 7 pre-set programmes 3 working freq.+autoscan Osteoarthritis 5 Hz Autoscan Osteoporosis Arthritis 10 Hz 20 Hz Fractures Articular pain

> Couple of professional solenoids

# MAG\_2000 LOW FREQUENCY, HIGH INTENSITY MAGNETOTHERAPY



• 28300 MAG 2000 MAGNETOTHERAPY - 2 channels - 300 Gauss 28311 MAG 2000 PLUS MAGNETOTHERAPY - 2 channels - 400 Gauss Ideal devices for domiciliary and professional magnetotherapy. 35 programmes: 20 pre-set programmes for the treatment of several pathologies, 14 programmes identified by the working frequency (from 1 to 100 Hertz) and an Autoscan programme with continuous frequency variation for the treatment of both hard and soft tissues at the same time.

MAG2000 PLUS has also the possibility to store 10 user memories choosing the frequency up to 120 Hz, intensity and therapy time: a great possibility for the professional user who need to use a specific treatment for each patient. Possibility to set the intensity of magnetic

field for all the programmes up to 300 Gauss (150 Gauss each channel) for MAG 2000 or up to 400 Gauss (200

Gauss each channel) for MAG 2000 Plus to easily treat different body parts through elastic therapeutic belt with 3 solenoids. Operating power 110-240 V.

Supplied with elastic therapeutic belt with 3

solenoids, couple of professional solenoids (28311 only), power supply, carrying bag and manual (GB, FR, IT, ES). On request DE.
• 28299 ELASTIC THERAPEUTIC BELT - spare

Belt with cable with 3 solenoids for low frequency treatments.

28316 COUPLE OF PROFESSIONAL SOLENOIDS

Couple of professional solenoids Ø 11 cm for high intensity therapy.

#### 35 PROGRAMMES (28300) - 45 PROGRAMMES (28311) 20 pre-set programmes 14 working freq.+autoscan Osteoporosis Intercostal Contusion 1 Hz 50 Hz Lumbalgy 60 Hz Arthrosis 3 Hz 70 Hz Arthritis Lumbar pain 5 Hz Cervical arthrosis Shoulder arthrosis 10 Hz 80 Hz Knee arthrosis 90 Hz Articular pain 15 Hz Cervical pain Periarthritis 20 Hz 100 Hz Sprains Coxarthrosis 30 Hz Autoscan Fractures Muscular Atrophy 40 Hz **Epicondylitis** Muscular contracture 10 memories (28311 only) **Epitrocleitis** Osteonecrosis

# OSTEOMAT 2000: MATTRESS FOR LOW FREQUENCY MAGNETOTHERAPY TREATMENTS

• 28307 OSTEOMAT 2000 MATTRESS FOR MAGNETOTHERAPY Osteomat has 4 sectors (2 active and 2 passive) linked with velcro straps to create a real mattress.

The two active sectors allow the biostimulation of a wide body part through 6 professional solenoids. The two passive sectors create a planar surface where patient can lay down. Each active sector can be personalized according to therapeutic needs by choosing solenoids positions.

The basic configuration of Osteomat 2000 stimulates the body zones (shoulders, column, pelvis) that are more affected by bone mass reduction. This is typical of osteoporosis disease. Suitable for MAG 2000 and MAG 2000 PLUS programmes.



# MT BASE: MAGNETOTHERAPY

#### • 28321 GIMA MT BASE PLUS - magnetotherapy

Magneto Base Plus + is an ELF low frequency magnetotherapic unit designed for domiciliary applications. The most important effects of the magnetic fields are: Antiedemigen / Analgesic / Antiphlogistic / Regenerative and have applications in: traumatology, rheumatology, angiology, neurology, dermatology, endocrinology. The magnetic field produced is impulsive. The internal generator produces square waveform electrical current with frequency varying from 10 to 99 Hz and impulse time varying so to obtain a field's intensity determinated from 10 to 80 Gauss. Internal sound sensor of magnetic field and safety system in case of short-circuit. Two transducers can be connected at the same time (the field produced by each transducer is half of the total).

• 28322 PLATE TRANSDUCER 70x120 mm - spare

- 28323 VELCRO ELASTIC BAND 100x8 cm spare

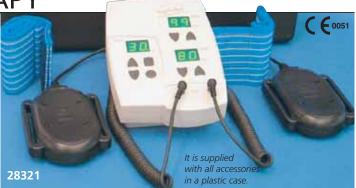
#### STANDARD ACCESSORIES

Power cable

1 velcro elastic band 100xh 8 cm

2 plate transducers 80 gauss - 120x70 mm 1 velcro elastic band 60xh 8 cm

ABS carrying case Manual (GB, IT)



#### TECHNICAL SPECIFICATIONS

Waveform: square Max. ratio emission/pause: 50%

Selectable magnetic field from 10 to 80 Gauss Size: 193x138xh 68 mm Selectable frequency: from 10 to 99 Hz Safety class: II BF - Norms: EN60601-1 (CEI)

Intensity of magnetic field: 80 Gauss (8mT) Operating voltage: 230V/50-60 Hz Weight: 1 kg

# **IONO BASE PLUS - GALVANIC IONOPHORESIS**

#### • 28306 IONO BASE - PLUS - 2 channels

Local administration of medicines by lonophoretics, electric osmosis and treatment of hyper hydrosis (sweating disease) and cellulitis. Current generator for hydro galvanization, aesthetic shaping and against cellulitis slight blemish. Microprocessor controlled, with selection of parameters and internal programs. Simple and safe to use, although it maintains characteristics of a professional equipment. Made in Italy.

- 28335 RUBBER ELECTRODES 50x50 mm box of 10
- 28336 SPONGE BAGS for electrodes 50x50 mm box of 10

#### **TECHNICAL SPECIFICATIONS**

Operating Voltage: 230 V - 50/60 Hz Absorbed Max Power: 10 VA

Size: 138x68x193 mm Max Output Current: 20 mA

Safety class: II BF - ( § 93/42/EEC. Made in Italy.

Supplied with ABS case, velcro elastic bands, rubber conductive electrodes 80x120 mm and 50x50 mm and envelopes sponges for electrodes.





Internal sprina

balanced

arm

allows

different

positions

Arm length 90 cm (45+45)

28306

# **INFRARED THERAPY LAMP - 250 W**

• 28652 INFRARED THERAPY LAMP - 250 W - desk with table clamp

• 28653 INFRARED THERAPY LAMP - 250 W - trolley

The infrared light relieves the suffering caused by sore muscles and joints ankylosis. The comfortable warmth created by infrared light penetrates deep into the skin, stimulates blood circulation and

warms the muscles. While the muscles are relieved, they automatically stretch and relax. At the same time, the blood circulation helps your body get rid of impurities and quickly sends oxygen-rich blood to stressed or aching muscles, causing an effective pain relief. Class II Electric.

• 28654 SPARE BULB - 250 W







• 28650 INFRAREX 230 V - 50/60 Hz

28651 SPARE BULB 7.5 W

Infrarex is a modern scientifically electronic therapeutic heating device which provides deep, infrared heat that can penetrate far below the surface of the skin to produce a shooting, comforting effect upon the nerves. It relieves muscular tension, reduce inflammation and provides pain relief without medication for many conditions such as: arthritis, bursitis, sinusitis, tennis elbow, back ache, neuralgia, muscular pains, aches, sprains, and other musculoskeletal aches. Infrarex provides pain relief without medication, you will experience pain relief within 10-15 minutes. No concern for side effects, simple to be used.

# MOMERT INFRARED LAMP 100 W

#### • 28648 MOMERT INFRARED LAMP 100 W

The lamp's deep penetrating infrared heat relaxes the muscles and stimulates the blood circulation. The pleasant heat expands the capillary veins, resulting in a better oxygen and nutrition supply to the tissues. Can be used for rheumatic diseases, allergies, cold diseases, alternative medicine (detoxification), beauty care. Operating voltage: 230 V - 50 Hz Multilanguage manual and box

28649 SPARE BULB - 100 W Philips

(GB, FR, IT, ES, PT, DE, HU, SK, LV, CZ, EE, PL, RU, BG).



Box size 185x140x225 mm

angle 28648



Adjustable

# **ISMART TENS - EMS**

TENS is a therapeutic technique mainly used for analgesic purposes in physiotherapy.

Suitable for a wide variety of pain therapies: acute or chronic pain, muscular pain, post-operative pain and also pains caused by pregnancy. It's usually divided according to its action mechanism

in tens conventional, tens endorphinic, tens sequential, tens maximum value, tens Burst.

EMS is a stimulating technique activating muscular contractions through electrical impulses.

As in TENS stimulation, impulses are applied to patient through electrodes placed next to the muscles to be treated.

In physiotherapy EMS is used for post-trauma and post-operative muscular rehabilitation and also as a complementary aid in sports activity and aesthetic treatments.

Basic programmes used in TENS treatments together with EMS classic protocols are combined in this product. SMART TENS offers a wide possibility to treat acute and chronic pains (TENS) and muscular strengthening and stimulation (EMS).

Supplied with 2 connection cables for electrodes, 4 pre-gelled electrodes with cable, belt clip, 4xAAA size batteries, user manual (GB, FR, IT, DE, ES) in a carrying bag.



TECHNICAL SPECIFICATIONS

- combined electrotherapy unit with 2 independent channels
- compensated biphasic square wave: current quantity from positive pole to negative one is constant to avoid hazardous thermal effect of polarization

Digital

keyboard

- 6 TENS stored programmes
- 5 EMS stored programmes
- 2/120 Hz waveform frequency
- 60 mA maximum intensity
- size: 68x110x31 mm
- 1 TENS free programme
- 1 EMS free programme
- 50/400 µs width impulse - power supply 4 batteries AAA Size
- weight: 85 g (without batteries)

28355

On line guick

guide on display



# Size: 162x10.7x120 mm **4 CHANNELS** LCD size: 31x37 mm 30 PROGRAMMES Weight: 200 g Manual: 28365 GB, FR, IT, ES, PT.

#### • 28342 GIMA 9 TENS - 2 channels

Pocket TENS with 9 programmes and 2 channels. 9 adjustable intensities.

Relieves muscle pain and stimulates blood circulation. Frequency: 2-80 Hz.

Supplied in a nylon bag with 2AAA batteries and 4 electrodes.

- 28351 GELLED ELECTRODES 40x40 mm pack of 4 spare
- 28343 CABLES pack of 2 pcs spare

#### • 28365 GIMA 30 TENS - 4 channels

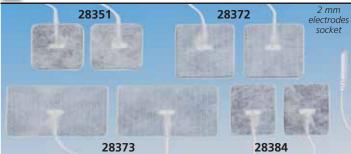
Portable electrical muscle stimulator with 4 channels and 30 programmes. Backlit LCD display.

Frequency: 2 to 2000 Hz

Supplied in a nylon bag with 4AA batteries and 8 electrodes

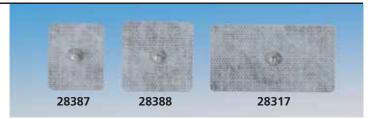
- 28366 ELECTRODES pack of 8 spare
- 28367 CABLES pack of 4 pcs spare
- 28368 AC ADAPTOR 230V 50Hz

# POSABLE GELLED ELECTRODES FOR ELECTROTHERAPY



**DISPOSABLE GELLED ELECTRODES WITH CABLE - latex free** High material flexibility allows easy application of electrodes on treated areas. Solid gel maintains the electrode adhesion and conductivity unchanged during procedure. The electrodes are equipped with 10 cm long cable, with 2 mm socket.

- 28384 GELLED ELECTRODES with cable 45x35 mm bag of 4
- 28351 GELLED ELECTRODES with cable 40x40 mm bag of 4
- 28372 GELLED ELECTRODES with cable 46x47 mm bag of 4
- 28373 GELLED ELECTRODES with cable 45x80 mm bag of 4



**DISPOSABLE GELLED ELECTRODES AND ADAPTORS - latex free** High material flexibility allows easy application of electrodes on treated areas. Solid gel maintains the electrode adhesion and conductivity unchanged during procedure.

- 28387 GELLED ELECTRODES 45x35 mm bag of 4
- 28388 GELLED ELECTRODES 46x47 mm bag of 4
- 28317 GELLED ELECTRODES 45x80 mm bag of 4
- 28390 2 mm CLIP ADAPTORS black box of 10
- 28391 2 mm CLIP ADAPTORS red box of 10
- 28392 4 mm CLIP ADAPTORS black box of 10
- 28393 4 mm CLIP ADAPTORS red box of 10



Dimensions:

60x135x19 mm

MIO-CARE - 2 CHANNEL TENS

• 28370 MIO-CARE TENS - 20 medical programmes

• 28376 MIO-CARE FITNESS - 55 programmes

(20 medical + 15 beauty + 20 fitness programmes)

• 28377 MIO-CARE PRO - 63 programmes

(14 medical + 15 beauty + 21 fitness + 13 free memories)

2 independent channels stimulator

- compensated biphasic square wave: avoids hazardous thermic effect of polarization

- easy to use, digital keyboard

- remaining therapy time and programmes instruction shown on graphic display

- internal rechargeable battery pack

- maximum intensity 200 mAh

- compliance with 93/42/EEC MDD

Supplied in a carrying bag with 2 connection cables with splitters, user manual (GB, FR, IT, DE, ES), 8 adhesive pads, internal rechargeable battery with battery charger.

 28372 GELLED ELECTRODES with cable 46x47 mm - bag of 4 • 28373 GELLED ELECTRODES with cable 45x80 mm - bag of 4

**( ( 0** 0476



MIO-CARE TENS

28370

Lipolysis - thighs Lipolysis - glutei and hips

Lipolysis - arms

Tissue elasticity

Capillarization

Heaviness in legs



13 FREE MEMORIES

Sequent. tonic contract. - upper limbs

Sequential tonic contractions - lower limbs

and trunk
Sequential phasic contractions -lower limbs

Sequential phasic contract. - upper limbs

Deep capillarization Muscle recovery

Agonist - antagonist

and trunk

Muscle relaxant

**50 PROGRAMMES** 

28377

#### 14 MEDICAL PROGRAMMES (all)

Tens conventional (rapid) Tens endorphinic (delayed) Tens maximum values Inflammatory Neck pain/cervicogenic headache Backache/sciatic pain Sprains/bruises

Vascularization Hand and wrist pain Plantar stimulation **Epicondylitis** Periarthritis

+6 MEDICAL PROGRAMMES (28370, 28376)

Atrophy prevention Atrophy (trophism rehabilitation)

Haematomas

Microcurrent Stress incontinence Urgency incontinence

#### 15 BEAUTY PROGRAMMES (28376, 28377)

Firming up - upper limbs Firming up - lower limbs Toning up - upper limbs and trunk Toning up - lower limbs Definition - upper limbs

and trunk Definition - lower limbs Modelling Microlifting Lipolysis - abdomen

#### 20 FITNESS PROGRAMMES (28376, 28377)

Warming up Resistance-upper limbs and trunk Resistance-lower limbs Resistant strength - upper limbs and trunk Resistant strength - lower limbs Basic strength - upper limbs and trunk Basic strength - lower limbs

Fast strength - upper limbs and trunk

Fast strength - lower limbs Explosive strength - upper limbs and trunk Explosive strength - lower limbs

+1 FITNESS PROGRAMME (28377 only)

Backlit display

**( (** 0476

# I-TECH PHYSIO PROFESSIONAL 2 CHANNELS STIMULATOR

#### • 28382 I-TECH PHYSIO PROFESSIONAL STIMULATOR

Professional stimulator with 2 indipendent channels

- compensated biphasic square wave: current quantity from positive pole to negative one is constant to avoid hazardous thermal effect of polarization
- monophasic square wave
- incontinence and ionophoresis programmes
- denervated treatment
- programmable TENS EMS memories
- adjustable frequency, width impulse, time, ramp
- remaining therapy time and programmes instructions shown on the LCD
- maximum intensity 200 mApp;

Can use same gelled electrodes with cable as Mio-Care

• 28381 IONOPHORESIS KIT - spare

(1 elastic band, 2 silicone conductive electrodes, 2 sponges)

Supplied in a carrying bag with:

- rechargeable battery and battery charger - 1 set of 4 pregelled electrodes 48x48 mm
- 1 set of 4 pregelled electrodes 50x90 mm
- 2 silicon conductive electrodes 60x90 mm
- 2 sponges 70x100 mm
- 1 elastic belt for electrodes fastening
- 2 cables, 2 mm connection male plug
- 4 cable splitter 2 mm male and female plug User manual (GB, FR, IT, ES)



PROGRAMMES: 21 NEMS 15 BEAUTY REHABILITATION

14 TFNS 9 UROLOGY 13 FREE MEMORIES

Digital

easv

to use

keyboard

# MIO IONOTENS, 2 CHANNELS • 28380 MIO-IONOTENS 37 programmes

2 channel stimulator for the customers who need an easy to use device with high output power and a complete list of TENS programmes, rehabilitation programmes and free memories. Portable and easy to use device with backlit display and digital keyboard. It is equipped with internal rechargeable battery (long-lasting) and belt clip. MIO-IONOTENS has 14 TENS programmes, 10 rehabilitation programmes including 3 ionophoresis treatments and 13 free memories (adjustable frequency, width impulse and time). Supplied in a carrying bag, with 2 cables, ionophoresis kit, 1 set of 4 pre-gelled electrodes (41x41 mm), 1 set of 4 pre-gelled electrodes (40x80 mm), belt clip, internal rechargeable battery, battery charger, user manual (GB, FR, IT, ES).

• 28381 IONOPHORESIS KIT - spare

(1 elastic band, 2 silicone conductive electrodes, 2 sponges)







# LATEX-FREE RESISTIVE EXERCISE BANDS

Latex-free bands available in 7 colour-coded levels of resistance and 3 lengths (1.5, 5.5 and 45 m).

These reliable and effective bands are ideal to improve strength, range of motion.

Use of these bands for resistive exercise provides force on the muscles.

Excellent for upper and lower body

Latex-Free Exercise Bands provide the same benefits as regular bands.

Latex-free band

Strength-elongation chart



Latex-free exercise bands - 1.5 m



# LATEX TONE LOOPS

#### • 47040 SET OF 4 TONE LOOPS

The closed-loop flat band fits comfortable around the upper and lower legs. It helps to exercise the muscles of hips and leas. 47040

2.4 x 58 cm

Set includes 4 below loops: each in a different colour-coded level. Tone loop 18 mm x 58 cm x 1.4 mm

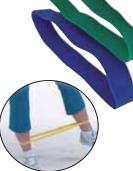
Tone loop 24 mm x 58 cm x 1.4 mm Tone loop 24 mm x 58 cm x 1.6 mm Tone loop 30 mm x 58 cm x 1.6 mm



1.8 x 58 cm







# **EXERCISE MATS**

- 47070 EXERCISE MAT 180x60xh 1.6 cm light blue
- 47080 EXERCISE MAT WITH HANG RING 180x60xh 1.6 cm green

Thick mats with sponge-like foam structure offer comfortable feeling. The closed-cell foam structure resists moisture. Easy roll for storage.



# RESISTIVE EXERCISE TUBING

Tubing is an affordable and convenient training tool which provides effective upper and lower-body workout. Elastic properties for resistive and strengthening exercise.

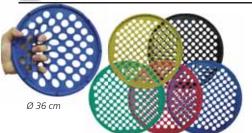


GIMA Code	LATEX EXERCISE TUBING	Thickness	Strength	Length
47060	Latex tube	1.5 mm	0	25 m
47061	Latex tube	2 mm		25 m
47062	Latex tube	2.5 mm		25 m
47063	Latex tube	3 mm		25 m
47064	Latex tube	3.5 mm		25 m



GIMA Code	LATEX TUBE WITH TPR HANDLES	Strength	Length
47050	Latex tube with TPR handles	0	125 cm
47051	Latex tube with TPR handles		125 cm
47052	Latex tube with TPR handles		125 cm
47053	Latex tube with TPR handles		125 cm
47054	Latex tube with TPR handles		125 cm

# HAND/FINGER/WRIST EXERCISERS



- 47130 GRIP TRAINER X-light
- 47131 GRIP TRAINER light
- 47132 GRIP TRAINER medium
- 47133 GRIP TRAINER heavy
- 47134 GRIP TRAINER X-heavy Releases typing and mousing tension.

Improves hand and finger flexibility. Excellent for finger and wrist strenghtening and rehabilitation.



 47160 SET OF 3 FINGER EXERCISERS Unique design for rehabilitation, excel-

lent stress-reliever for users. Simply insert fingers into circles and stretch.

Multiple resistance level available, set of light, medium and heavy resistance.



- 47140 SQUEEZE EGG X-soft
- 47141 SQUEEZE EGG soft
- 47142 SQUEEZE EGG medium
- 47143 SQUEEZE EGG firm
- 47144 SQUEEZE EGG X-firm

These gel-filled eggs offer variable resistance training for hands and fingers. Help grip strengthening and reduce

stress.





38 mm

- 47171 TPR FLEX BAR medium
- 47172 TPR FLEX BAR heavy

Flex bar is a flexible, durable resistance device with ridge surface for enhanced grip during use.

It is used to improve grip strength by bending, twisting or vibrating.



- 47180 POWER GRIP light
- 47181 POWER GRIP medium
- 47182 POWER GRIP heavy

Develop finger flexibility, strength and coordination.

Increase hand, wrist and forearm strength. Improve the injured finger recovery.



• 28790 HAND GRIP METER - plastic Indicator remains at maximum until reset and is calibrated 0-75 kg. Size 20x15 cm.

Sold in a blister.

Manual in: GB, FR, IT, ES.

# BALANCE AND WEDGE CUSHION



## 47090 • 47090 BALANCE CUSHION

#### 47095 WEDGE CUSHION

Non allergic, non toxic air filled cushions made of soft, pliable material free of latex, PVC, phthalates and chloride. Both have two surfaces: smooth and bubbled which provide two kinds of user experience. Great for improving

intramuscular coordination as well as balance training ergonomic sitting and rehabilitation.

# RESISTANT BALLS

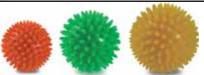
• 47102 BURST RESISTANT BALL - Ø 55 cm • 47103 BURST RESISTANT BALL - Ø 65 cm • 47104 BURST RESISTANT BALL - Ø 75 cm •

Designed for dynamic workouts that incorporate moderate level of resistance.

Deflate slowly if punctured. 300 lb burst resistance level.

47104 47102 47103

# **MASSAGE BALLS**



 47120 MASSAGE BALLS Set of 3 massage balls Ø 6, 7, 8 cm





136 kg burst resistance level

# **NASAL WASH**



• 28083 SINUS C SALINE NASAL SPRAY 20 ml - for children - box of 48 • 28084 SINUS A NASAL WASH - for adult - bottle 120 ml + 12 saline sachets Nasal wash helps to remove the sinus symptoms such as runny nose, nasal dryness and nasal congestion. By performing a nasal wash, you can remove particles such as pollen and dust in order to reduce the mucous membranes inflammation and make it more resistant to allergies.

# **HUMI-RAINBOW**

adjusted in direction (360° rotative head) and speed (adjustable knob)







• 28110 VAPINAL THERMAL WATER INHALER Warm jet mineral water inhaler ideal for home spring water inhalation treatment. It delivers hot humid steam through a nozzle working with the Venturi system and mixing the steam with the principles of thermal water. Equipped with stainless steel boiler working with resistance at 230V-50 Hz. Supplied with polycarbonate ampulla. Made in Italy.

• 28112 VAPINAL AMPULLA - spare part

#### TECHNICAL SPECIFICATIONS

Capacity: 800 ml Steam boiler in stainless steel Security valve and thermostat

Operating voltage: 230 V - 50 Hz - 600 Watt

Heating time: 5-8 min

Inhalation time (for 1 l): 12-15 min



• 28070 HUMI-RAINBOW HUMIDIFIER A cold-mist ultrasonic humidifier with an actractive design and cromatic 7-led colours change

• 28071 BALSAMIC **ESSENCE** - pine

• 28072 BALSAMIC **ESSENCE** - citrus

#### TECHNICAL SPECIFICATIONS

Power feeding: AC 110-240V / 50-60 Hz Max mist output: 280 ml/h Water Tank capacity: 2.8 l Suitable for room size: min 10, max 25 m<sup>2</sup> Max operating hours (non-stop): 10 hours Size (individual box): Ø 19xh 30 cm - Weight: 1.4 kg

## ACCESSORIES FOR ANY BRAND OF NEBULIZER ACCESSORIES FOR NEBULIZER

Gima offers different nebulizer bulbs with their line of accessories, suitable for any brand of nebulizer.



GIMA code	NEBULIZER ACCESSORIES	To be used with
Standard	d accessories with Famiglia, Corsia,	, Eolo
28158 28139 28146 28147 28157	PVC connection tube - 1m Nebulizer bulb Facemask - adult* - replaces 28143 Facemask - paediatry* - replaces 28144 Mouthpiece - nasal prong	all nebulizers all nebulizers bulb 28139/28140 bulb 28139/28140 bulb 28139/28140
28138 28140	Nebulizer kit adult and pediatric facemask, pvc-tube, bulb, r Nebulizer bulb	all nebulizers nasal prong, mouthpiece all nebulizers

#### FASTERJET BULB

with Valve System

A new designed Jet Nebulizer capable of delivering any medication in a very short time with a high amount of respirable particles. The Valve System makes therapy extremely efficient by reducing the amount of wasted medication while optimizing the output to the patient.

#### **TECHNICAL SPECIFICATIONS FASTERJET**

Capacity: 16 ml Neb rate: 0.60 ml/min Respirable volume: <5 µm 80% Residual volume: 0.8 ml

MMAD (Mass Median Aerodinamic Diameter): 2.7 µm

Fasterjet bulb: For delivering any medication in a very short 28163 + 28165

28164 28166 28168 28169 28145

	GIMA code	NEBULIZER ACCESSORIES	To be used with
28	8163	Fasterjet bulb*	all nebulizers
		with Valve System	
28	8164	Nebjet bulb **	all nebulizers
		with Double Venturi Effect	
28	8165	Mouthpiece bi-valve	bulb 28163
28	8166	Mouthpiece .	bulb 28164,
28	8167	Nasal Prong	bulb 28164, 28163
28		Facemask-adult***	bulb 28164, 28163
28	8169	Facemask-pediatry***	bulb 28164, 28163
28	8145	Filter - spare	28130/1/2/3/4/5
* C+	* Standard with Happynob II Haspynob ** Standard with Happynob I III Potanob		

Standard with Happyneb II, Hospyneb \* \* \* Without elastic

\*\* Standard with Happyneb I, III, Betaneb

\*With elastic

# FAMILY AND PINGOO ULTRASONIC NEBULIZERS



code	OLI KASONIC NEBOLIZERS	28117	
28106	Family ultrasonic nebulizer		
28117	Pingoo ultrasonic nebulizer		
28113	Re-chargeable battery Ni MH 1	2 VDC - Fam	nily - optional
28115	Re-chargeable battery Ni MH 12 VDC - Pingoo - optional		
28114	Spare Kit: includes adult and paediatric facemask,		
	nasal prong, mouthpiece and tube		
28121	() ()		
28122	Medication cups Pingoo (box	of 15 pcs.)	







#### **ULTRASONIC NEBULIZERS**

Thanks to the innovative electronic technologies these easyto-use ultrasonic nebulizers provide a quiet, fast and portable operation with optimal particle size.

Portable: small and lightweight, it allows patients to perform treatments anytime and anywhere.

Optimal particle size: particle size determines the extent to which the medication can be inhaled by the patient into the deep lung tissue.

Approx 90% of particles generated by Family or Pingoo have the optimal 1-5µ (microns) size.

Fast treatment: with its high-efficiency design,

it allows a quick treatment time, most within 6 minutes, with

limited power consumption. Low noise level: treatments

are not only fast but are virtually silent due to its advanced ultrasonic technology.

Rechargeable battery - optional 8 languages user

manual: GB, FR, IT, DE, ES, PT, GR, SA.

28106

#### **TECHNICAL SPECIFICATIONS**

Operating voltage: 220-240 V 50/60 Hz Power: 10 W

Ultrasonic frequency: 2.5 MHz

Nebulization time: 0.2-0.7 ml/min depending on medication density

Medication cups capacity: max 8 ml Family, max 4.5 ml Pingoo

Automatic switch-off

Particle size: 5 µ (microns) average Three programmable flow levels

Noise level: <40 dB

#### **STANDARD ACCESSORIES**

Adult facemask (only Family) Paediatric facemask Nasal prong, Mouthpiece Connection tube

Medication cups Transformer (220-240V-12V DC)

HHEB

**C €** 0434

Carrying bag User manual



• 28075 MESH NEBULIZER

28078 MESH 2 NEBULIZER since 2018

Small, handy, lightweight nebulizer for the treatment of respiratory diseases such as asthma, allergies,

Can operate with 2xAA standard batteries or optional AC adaptor 100x240 V.

- maximizes the benefits of medicine

- portable, handheld design (only 120 mm height)

- ultra-low noise and ultra-light design

- one-button operation for easy use

- for adult and child: noiseless use and compact design allow to make inhalation even while children are sleeping 28075

- multilanguage box: GB, IT, FR, ES
Supplied with cover\*, connector\*, adult and child mask, mouthpiece, 2xAA batteries, carrying bag, manual (GB, IT, FR, ES)

• 28076 RESPIRATORY ACCESSORY KIT (adult and child mask, mouthpiece and connector), space for 28075

mouthpiece and connector) - spare for 28075 • 28077 AC-DC ADAPTER 100-240 V - optional

28079 RESPIRATORY ACCESSORY KIT

(adult and child mask, mouthpiece) - spare for 28078

#### **TECHNICAL SPECIFICATIONS**

Power supply: Ultrasonic frequency: Nebulizer rate: Max. / min. liquid volume: MMAD Nebulizing head life: Battery life:

Automatic shutdown:

2xAA batteries or adapter (AC-DC 3V 1A) - 2 W approximately 140kHz ≥0.2ml / min

8ml / 0.5ml approximately 5µm

90 minutes with two AA alkaline battery automatic shutdown without liquid

28078

Type B. Class II

# MYNEB NEBULIZER

• 28073 MYNEB NEBULIZER - piston Compact, fast and silent nebulizer. Suitable for the treatment of the respiratory tract diseases, bronchial and asthmatic diseases, allergies. Ideal for nebulizing any medicine, ever oily ones such as cortisones

essentials oils, and active ingredients with solid elements (suspensions).

Supplied with carrying bag, fasterjet bulb, adult and pediatric mask, air tube, mouthpiece and nosepiece.

Multilanguage box and manual: GB, FR, IT, ES, DE. Class IIa. Made in Italy.

• 28093 FILTER spare - box of 3

Noise level:

Size and weight:





input 100-240 V - 50/60 Hz - 0,6 A AC adapter:

output 12 V - DC 2A Operating cycle: 30/30 min. ON/OFF

51 dB

Nebulization rate: 0.45 ml/min with NaCl 0.9%

Air Flow: 12 l/min Max pressure: Particle size:

165 kPa/1.65 bar 75% < 5 µm (NaCl 0.9%) 132x140xh 60 mm - 450 g



# HAPPYNEB NEBULIZERS FOR DOMESTIC USE - PISTON

• 28132 HAPPYNEB II NEBULIZER - piston 230V- Faster-Jet

• 28135 HAPPYNEB III NEBULIZER - piston 230V

Happyneb stylish and portable piston nebulizer for a quick and

efficacious aerosol therapy.

Made in Italy.

Reliable, practical and safe.

Noiseless and lubrication free.

Unit includes an air filter to be replaced every 70 applications, and handle for

easy carrying.

It is built in accordance with European Standard EN 60601-1.

5 languages box and manuals: GB, FR, IT, ES, DE

• 28145 FILTER - spare

28135



Nebjet bulb

#### **NEBULIZER TECHNICAL DATA**

Happyneb III with Nebjet Happyneb II with Fasterjet Capacity: 12 ml 16 ml Respirable volume < 5 µm 75%

MMAD (Mass Media Aerodinamic Diameter) 2.32 µm 2.7 µm 0.60 ml/min Neb rate 0.45 ml/min Residual volume 0.7 ml 0.7 ml

#### STANDARD ACCESSORIES

Adult and pediatric face mask Mouthpiece

Fasterjet bulb (28132 only) Nasal prong Connection tubing Nebjet bulb (28135 only)

Nebulizing time: 1 cc about 3 minutes

Voltage:
Maximum pressure:
Operating pressure:
Air flow:
Dimensions:
Weight:
Noise level
Temporary use:

Class of risk - norms

TECHNICAL SPECIFICATIONS		
28132 - HAPPYNEB I	I 28135 - HAPPYNEB III	
<b>├</b> 2	230V/50 Hz ————	
280 kPa	250 kPa	
110 kPa	90 kPa	
15 l/min	14 l/min	
3 <sup>,</sup>	1x22x13 cm ————	
2.3 kg	2 kg	
58 db	58 db	
Continuous use	30/30 min ON/OFF	
⊢ Ila - 0	Class II, Type B ————	

# ATOMIZER 2 SPEEDS, PISTON NEBULIZER FOR FAMILY USE

#### • 28094 ATOMIZER NEBULIZER - 2 speeds

Piston-type compressor with 2 speeds for family use. With accessory compartment separated from cord compartment for improved hygiene. Made in Italy.

• 28093 FILTER - spare - box of 3

#### **TECHNICAL SPECIFICATIONS**

230 V - 50 Hz Operating voltage: Operating cycle: continuous

speed 1: 45 kPa - speed 2: 60 kPa Operating pressure: speed 1: 8 l/min - speed 2: 11 l/min Air Flow: speed 1: 0.2 ml/min - speed 2: 0.35 ml/min Nebulization rate:

Particle size:  $80\% < 5 \mu m$ 1.85 bar / 185 kPa Max pressure:

157

1.4 kg Weight: Noise level: 56 db Class of risk: Ila Standard accessories

28094

**C €**0434

FASTER-JET BI-VALVE BULB FOR A QUICKER DELIVERY OF PARTICLES

28132

#### STANDARD ACCESSORIES

Nebjet bulb with connector Adult and child mask Mouth piece and nose piece Air tube and 3 air filter



# • 28097 EOLO NEBULIZER - piston

• 28091 EOLO NEBULIZER - piston - UK plug Innovative, portable, easy to use nebulizer for home use, recommended to nebulize antibiotics and bronchodilator drugs. Plastic body with high thermal insulation. Supplied



• 28102 MISTRAL NEBULIZER - piston

Compact portable nebulizer for home use.

Duty cycle: 20 min on / 40 min off

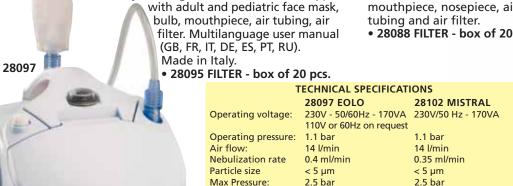
22x14.5x12 cm - 1.7 kg

insulation class, Type B

Supplied with Hi Flo bulb, adult and pediatric mask with string, mouthpiece, nosepiece, air

60 db

Italy



Noise level (EN 13544-1) 55 db

lla

Italy

Dimensions:

Class of risk

Norms: Origin:



Accessories compartment

# NEBULIZERS FOR PROFESSIONAL AND HOSPITAL USE



#### **PROFESSIONAL NEBULIZERS**

Piston compressor nebulizers for professional and home care use. They embodies all the dictates of modern aerosol therapy techniques. Reliable and simple to use, also by inexperienced users. Manual: GB, FR, IT, DE, ES. Made in Italy.

GIMA code	PROFESSIONAL NEBULIZER	Voltage
28134	HOSPYNEB PROFESSIONAL	230 V - 50/60 Hz
28137	HOSPYNEB PROFESSIONAL	110 V - 60 Hz
28090	COMP-A NEB PROFESSIONAL	230 V - 50 Hz
28089	NASALJET	-
28176	COMPRESSOR - spare for 28134	230 V - 50/60 Hz
28145	FILTER - spare	



**HOSPYNEB** COMP-A NEB Operating voltage: 230 V - 50 Hz 110 V - 60 Hz 110 V - 60 Hz on request 230 V - 60 Hz 230 V - 60 Hz on request 28x19xh 17 cm 350 kPa (3.5 bar) 19.6x35.7xh 18.5 cm Max pressure: Noise level: 250 kPa 60 dBA 55 dBA 0-130 kPa (0-1.3 bar) Operating pressure: 0-110 kPa Weight: Air Flow: 4.1 kg 2.5 kg 15 l/min MDD class:

#### STANDARD ACCESSORIES

Fasterjet nebulizer with valve system Nosepiece irrigation (polypropylene) Mouthpiece (polypropylene) with valve (silicone) Adult and child mask (PVC DEPH free) Air tube (PVC DEPH free) and spare filter. Nasaljet (only with 28090).



28092

and electric insulation plastic chassis in accordance with the latest European Safety regulations. The oil-free piston compressor has long durability and is equipped with the highly efficient HI-FLO jet nebulizer to guarantee quick and accurate drug delivery. Easy to handle and transport.

• 28104 FILTER - spare - box of 2

#### TECHNICAL SPECIFICATIONS

Operating Voltage: 220-230 V - 50/60 Hz Power consumption: 184 VA Max pressure: 250 kPa (2.5 bar)

Air flow: 16 l/min

Operating pressure: 130 kPa (1.30 bar) Operating air flow: 5.2 l/min at 130 kPa

Nebulization rate: 0.50 ml/min with 4 ml solution MMAD: 3.25 μm GSD: 3.45

Size: 255x190xh 105 mm Weight: 2.2 kg Noise level: approx 57 db Made in Italy

#### STANDARD ACCESSORIES

HI-FI O Jet bulb Mouthpiece Adult and child mask Air tube and air filter Multilanguage user manual: GB, FR, IT, ES, DE, PT

# NEBULIZER FOR INTENSIVE HOSPITAL USE

Made in Italy

28105

#### • 28060 CLINIC-AIR NEBULIZER - piston

High performing piston nebulizer for administration of any kind of drug, ideal for intensive hospital and clinical use. Its structure is made of a high thermal and electrical insulated plastic in accordance to safety European standards.

Long life dry piston compressor and bulb with a valve system that allows to adjust the nebulization speed.

Class IIa - Insulation class (EN60601-1): Class II Type B.

#### **TECHNICAL SPECIFICATIONS**

Operating Voltage: 230 V - 50/60 Hz Max pressure: 250 kPa (2.5 bar) Operating pressure: 130 kPa (1.30 bar)

Nebulization rate:

Power consumption: 110 VA Air flow: 16 l/min

CONTINUOUS

SE COMPRESSOR

Operating air flow: 5.2 l/min at 130 kPa

• 28062 BULB - spare • 28063 FACE MASK -

adult - spare

28064 FACE MASK -

pediatric - spare

• 28104 FILTER - spare box of 2

#### STANDARD ACCESSORIES

Bulb with valve Mouthpiece Adult and child mask Air tube and air filter Multilanguage user manual: GB, FR, IT, ES, DE





# MEDICAL GRADE SILICONE TUBES FOR EXTERNAL USE



SILICONE TUBES for external medical use - silicone 100% Suitable for autoclaving (135°C - 2.2-2.5 bar) and Gamma Sterilization. Resistant to hot air up to 200°C. Infra-red vulcanization.

Hours treatment at 200°C temperature in special oven. Anti-adherent, avoid incrustation and coagulation. Medical Grade - Transparent - Odourless

#### **TECHNICAL SPECIFICATIONS**

Raw material: HTV-R-401/60 S - WACKER (D) Colour: translucent

Colour: translucent
Hardness: 60° ±5% Shore - DIN 53505
Density: 1.17 g/ccm - DIN 53479A
Tensility: 10.8 N/mm² - DIN 53504 51
Stretch: 490/530% - DIN 5350451
Tear resistance: 34-35 N/mm - ASTM D 624 B
Reverse pull elasticity: 51% - DIN 53512
Compression set: (22h/175°C): 30-15% - DIN 53517

Made in European Union according to: US PHARMACOPOEIA XXI EUROPEAN PHARMACOPEA DIN 58367 - DIN 58362 - DIN 13098- FDA 177.2600 - BGA XV part A and B - BGA IX part B

#### MADE TO ORDER SILICONE TUBES

We can manufacture any size (minimum order 500 m - delivéry 30 days)

GIMA	Internal diameter	Thickness	Minimum
code	x external diameter	mm	order
25450	1x3 mm	1 mm	roll of 100 m
25451	2x4 mm	1 mm	roll of 100 m
25452	3x5 mm	1 mm	roll of 100 m
25453	4x6 mm	1 mm	roll of 100 m
25455	6x8 mm	1 mm	roll of 30 m
25458	3x6 mm	1.5 mm	roll of 30 m
25459	4x7 mm	1.5 mm	roll of 30 m
25460	5x8 mm	1.5 mm	roll of 30 m
25461	6x9 mm	1.5 mm	roll of 30 m
25462	7x10 mm	1.5 mm	roll of 30 m
25466	4x8 mm	2 mm	roll of 30 m
25467	5x9 mm	2 mm	roll of 30 m
25468	6x10 mm	2 mm	roll of 30 m
25469	8x12 mm	2 mm	roll of 30 m
25470	10x14 mm	2 mm	roll of 30 m
25474	5x10 mm	2.5 mm	roll of 30 m
25475	7x12 mm	2.5 mm	roll of 30 m
25476	8x13 mm	2.5 mm	roll of 30 m
25477	10x15 mm	2.5 mm	roll of 30 m
25480	6x12 mm	3 mm	roll of 30 m
25481	7x13 mm	3 mm	roll of 30 m
25482	8x14 mm	3 mm	roll of 30 m
25483	9x15 mm	3 mm	roll of 30 m
25484	10x16 mm	3 mm	roll of 30 m
25485 25488 25491 25495	12x18 mm 8x15 mm 10x20 mm made to	3 mm 3.5 mm 5 mm	roll of 30 m roll of 30 m roll of 30 m roll of 30 m 500 m

# **ACCESSORIES FOR ANY SUCTION ASPIRATOR**



- SILICONE VACUUM SUCTION See page 172
- SUCTION CATHETER See page 43
- S/S FRAIZER SUCTION CANNULA See page 34
- S/S ROSEN SUCTION CANNULA See page 34
- S/S NOVAK SUCTION CANNULA See page 33

# BREAST PUMP - MAMILAT GIMA

• 28148 MAMILAT - BREAST PUMP - 230 V - 50 Hz

Easily transportable from one maternity ward to another, or for use at home. To be used for mother's milk suction. Made of highly heat-resistant, electrically insulated plastic material in conformity with the latest European safety standards. Supplied with 2 polycarbonate milk bottles (150 cc and 250 cc) antibacterial and hydrofobic filter, set of tubes 6x10 mm, breast shield, PVC air tube. Suction adjustment knob. Working time: 20 minutes ON, 40 OFF.

• 28229 HYDROPHOBIC ANTIBACTERIAL FILTER - spare

28149 SPARE KIT

Includes two plastic bottles (125 cc and 250 cc) nipple shield, filter and tubes.

#### **TECHNICAL SPECIFICATIONS**

Regulator for suction intensity - max suction -0.33 bar Operating voltage: 220-230 V - 50/60 Hz - available on request 110 V - 60 Hz Max flow (air litres/min): 14 l/min Power consumption: 184 VA

Size: 235x190x165 mm Weight: 2.2 kg Norms: CEI 62-5 (IEC601-1). Made in Italy

5 languages manual: IT, GB, ES, FR, DE. 28149



# RES-Q-VAC FILTERED HAND SUCTION

#### • 28124 RES-O-VAC (FILTERED) SUCTION

This lightweight and hand held suction unit requires no batteries or electricity and yet provides powerful suction whenever and wherever you need it.

It offers ultimate safety and ease of use for the professional and fits easily into any emergency bag or ambulance. **Key Features:** 

- portable Hand Powered Suction one hand operation
- hospital suction level performance >600mmHg
- always ready to go, no set up required, no batteries to recharge
- patented 0.22 equivalent micron filter for ultimate infection control
- full stop protection filter prevent fluid overflow
- easy snap on replacement canister sets with Adult and Child catheters
- each unit 100% tested for reliability



Kit includes: Res-q-Vac pump, canister 300 ml with filter, soft cannula Ø 12.7 mm x 20.3 cm length

- 28128 SPARE ADULT KIT with filter Includes canister 300 ml and wide soft adult style yankauer. Disposable.
- 28129 SPARE PEDIATRIC KIT with filter Includes canister 300 ml and 2 pediatric catheters with different length: 356 mm for paediatric and 88.9 mm for neonatal applications. Disposable.

28124



Jar 300 ml

#### **TECHNICAL SPECIFICATIONS**

Weight: 143 g Size: 114x180x55 mm Max vacuum: > 600 mmHg Min. vacuum after 2 activations: > 400 mmHg Volume per stroke: 30 ml Capacity before full: 290 ml Inner Ø of adult catheter: 9.53 mm Length of adult catheter: 272 mm

Pump is suitable for cold or ETO sterilization





# HAND/FOOT/KNEE SUCTION PUMP

• 28220 TOBI MANUALE - manual suction aspirator Independent of any power source, Tobi Manuale is simple to operate pressing pedal by foot, hand or knee. It is used to clear patient's airways safely and efficiently, anytime, anywhere. Precision and solidly built to assure long service life. Polycarbonate suction bottle

with capacity 400 cc, autoclavable at 120°C and spill-over protection. Bacterial filter included. Multilanguage user

manual: GB, FR, IT, DE, ES. • 28219 BOTTLE

0.4 I - spare • 28229 **HYDROPHOBIC ANTIBACTERIAL FILTER - spare** 

**C E**0476



Weight: 1.2 kg Size: 225x165x85 mm Max suction -0.40 bar Bottle capacity: 400 cc Suction power: 22 l/min Made in Italy

# HAND SUCTION PUMP

#### • 28180 HAND SUCTION UNIT

Designed to provide quick and effective pharyngeal and tracheal suction for emergency use.

The adjustable stroke knob provides different suction pressure. Supplied with 250 ml bottle and 2 sterile adult

cannulas 26 and 40 cm • 28181 SPARE ADULT KIT Includes 250 ml bottle and 2 sterile adult cannulas 26 and 40 cm.

> $C \in$ Jar 250 ml <

Supplied with multilanguage box and manual: GB, FR, IT, ES, DE, PT, PL, GR, Arab.



Max vacuum: -450 mmHg Peak free airflow: >20 l/min Size: 185x70x168 mm External diameter of catheter connection: 13.35 and 8.67 mm Peak free airflow: >20 l/min

Weight: 260 g

# SPENCER JET COMPACT 300D PORTABLE SUCTION UNIT

lar 400 ml

#### 28177 JET COMPACT PORTABLE SUCTION UNIT

Extremely compact suction device to be used to remove fluids from the airway or respiratory support system. The device creates a negative pressure that draws fluids through disposable tubing that is connected to the collection container. Easy view of the setted vacuum thanks to the LED indicators. Classification ISO: high vacuum / high flow. Supplied with 12 V power cable, battery, disposable container with filter, disposable patient tube.

28178 DISPOSABLE CONTAINER 300 ml with filter

#### • 28179 POWER ADAPTER

Dimensions: Weight: 1.60 kg Vacuum range: Flow (free flow): 32 l/min 70 dB Electrical connector requirement: 0.75 A max: 12 VDC

**TECHNICAL SPECIFICATIONS** 245x70x185 mm from 50 to 550 mmHg 100-240 VAC 47-63 Hz

IP grade 12 V DC Ni-MH Battery: Battery operative time: 30 min ON, 30 min OFF Battery recharging time: 5 h Container capacity: 300 ml Patient tube length: 1 m



Class IIa Medical Device according to Dir. 93/42/CFF

# MINIASPEED BATTERY EVO PROFESSIONAL SUCTION ASPIRATORS

- 28282 MINIASPEED EVO BATTERY SUCTION 1 I
- 28283 MINIASPEED EVO BATTERY SUCTION 1 I for ambulance
- 28284 MINIASPEED EVO BATTERY SUCTION 2 I

Professional portable high flow - high vacuum aspirators with integrated rechargeable batteries. It works at 12 V power supply with rechargeable batteries or directly by mains supply, continuously at 110-230 V while recharging batteries. Up to 45 minutes of autonomy with fully charged battery. Made in Italy.

- 25480 SILICONE TUBE 6x12 mm roll of 30 m
- 28254 ADAPTER FOR CATHETER
- 28255 HYDROPHOBIC 99% BACTERIAL FILTER
- 28258 AUTOCLAVABLE JAR 1000 ml (with cover)
- 28259 DISPOSABLE SUCTION LINER

28294 AUTOCLAVABLE JAR 2,000 ml (with cover)

Courtesy lamp

#### **TECHNICAL SPECIFICATIONS**

with battery DC 12 V Operating voltage:

with power supply 100÷240 V ~ 50/60 Hz - 14 VDC 4,28A Power consumption: max 50 W

134x378xh 263 mm Weight: 4.7 kg (5 kg version for ambulance)

Bottle capacity: 1,000 or 2,000 ml Flow: 30 air litres/min Sound level:

65 dBA at 1 m Operating cycles: continuous (45 minutes battery autonomy)

MAX vacuum:  $0 \pm 85 \text{ kPa}$ 

Internal battery 12 VDC 4A h lead hermetic

Battery autonomy: Norms:

about 45 minutes, recharging time approx 6 hours MDD 93/42/EEC (Class IIa - annex IX) EN60601-1(IEC 60601-1) / EN60601-1-2 (IEC 60601-1-2)

UNI EN ISO 10079-1/ UNI CEI EN ISO 14971 Degree of protections against ingress of liquids: IP34d (IEC 529)



#### STANDARD ACCESSORIES

Autoclavable 1 or 2 l jar with safety valve Power supply cord - 2 m Sterile disposable cannula CH14 Sterile disposable manual regulator Disposable silicone liner 1 l (28282-3 only) 2 bacterial hydrophobic filters

Cigarette lighter power cord (28282, 28284 only) User manual: GB, IT, FR, DE, ES

Shoulder carrying bag Multivoltage battery charger Silicone tubing set Ø 6x12 mm Support bracket for ambulance (only 28283)

**PROXIMITY** 

# SUPERVEGA EVO BATTERY AMBULANCE ASPIRATOR

• 28182 SUPERVEGA EVO AMBULANCE BATTERY ASPIRATOR

• 28183 SUPERVEGA EVO BATTERY ASPIRATOR

Supervega Evo is an electric medical device for the nasal, oral and tracheal aspiration of body fluids in children or adults. Two or three options of operation: by 100-240V power feeding (28183 only), 12 V car adapter or internal rechargeable battery. Large LCD for clear reading of vacuum values along with soft keys for vacuum adjustment increase the accuracy of aspiration. Smart operation thanks to the combination of the lightweight lithium-ion battery with the innovating FEEDBACK system that controls and manages the power of aspiration, providing a long autonomy of the battery and quiet noise level during operation. The PROXIMITY function to switch ON or OFF the device without touch prevents and avoids cross-contamination in-between patients. Equipped with a long-life brushless motor eliminating any type of smell and coal residuals. Various options of jar: standard autoclavable polycarbonate (121°C), optional FLOVAC® disposable liners or APEC® that can resist up to 143°C, see at page 163. Complies with EN 60601- 1-11 only 28183 "for use in the home healthcare environment" and carries IP21 degree of protection. Made in Italy.

TECHNICAL SPECIFICATIONS

Oil-less and maintenance-free piston pump Motor:

Internal rechargeable Lithium battery (14.8 V - 5.2 A) - Autonomy 70 min Power: Car-ambulance adapter (12 V - 4 A) - only 28183

AC/DC adapter 110-230 V, 50-60 Hz - only 28183 Recharge from support bracket - only 28182 Max vacuum (adjustable): -0.75 Bar; -75 kPa; -563 mmHg

Max free air flow rate: 26 l/m Size: 35x19x15 cm Duty cycle: non stop operation (by mains or 12 V only)

Weight: 2.7 kg

RMP FEEDBACK Carrying handle LITHIUM BATTERY LCD DISPLAY AUTOMATIC VACUUM CONTROL B 28182

STANDARD ACCESSORIES

Polycarbonate jar 1,000 ml with overflow valve system Antibacterial filter Suction catheter

Silicone tube set with conical connector

Universal power adaptor (100-240V - 50/60 Hz) (only 28183)

12V car adapter (only 28183) Support bracket for ambulance 20x16x16 cm (only 28182)

Carrying bag (only 28182)

User Manual GB, FR, IT, DE, ES.



AC/DC adapter (28183 only)

for ambulance (28182 only)

# SUPER VEGA BATTERY SUCTION ASPIRATOR ON TROLLEY



• 28193 SUPER VEGA BATTERY on trolley - suction 2x2 l

Portable suction unit for the aspiration of body liquids, oral, nasal and tracheal aspiration in adults or children. For professional use and with a powerful aspiration of max 36 l/min. It comes with double collection jars and on a stand with five castors for easy transport.

Two different working options: AC/DC adapter, rechargeable battery make it a versatile suction unit approved for NON-STOP operation without overheating.

Provided with visual and acoustic alarm indicating low battery level, vacuum-meter (bar & kPa) and vacuum regulator.

32x30xh 99 cm - 7.9 kg Operating voltage: 100-240 V - 50/60 Hz

Internal rechargeable Pb battery: 12V - 4A

**TECHNICAL SPECIFICATIONS** Battery autonomy:

60 min 36 air litres/minute Flow: User manual: GB, FR, DE, IT, ES

Recharging: 240 min Temporary use: 120 on - 60 off Made in Italy

1 I jar with overflow safety valve

36 l/min.

# **BATTERY SUCTION ASPIRATORS**

• 28243 SUPER VEGA BATTERY - plastic case - 16 l/min. • 28190 SUPER VEGA BATTERY - plastic case - 36 l/min.

28213 TROLLEY FOR SUPER VEGA
28242 BATTERY FOR SUPER VEGA/TOBI (28243\*/28240) - spare

28251 BATTERY FOR SUPER VEGA (28190/28243\*\*) - spare

\*Up to S.N. 2141 (3 LEDs)

\*\*Since S.N. 3000 (1 LED)

With incorporated rechargeable batteries. It can operate at 12 V power supply at rechargeable batteries and, thanks to an electronic system, at 230 V while recharging batteries.

Autonomy: approx 45-50 min (28243), 60 min (28190)

Recharging time: 120-150 minutes.

Max suction: -0.75 bar (28243) -0.80 bar (28190)

Suction power: 16 or 36 air litres/min It has unbreakable 1,000 ml standard bottle

(2,000 ml optional) autoclavable at 120°C with safety float control valve to prevent overflow.

#### TECHNICAL SPECIFICATIONS SUPER VEGA

Operating Voltage: 220-230 V - 50/60 Hz AC - 12 V DC (28243) 100-240 V - 50/60 Hz (28190)

Size: 350x210x180 mm Weight: 4.9 kg

28259 28258

Max suction -0.75 bar (563 mm/Hg) (28243), -0.80 bar (28190) Suction power: 16 air litres/min (28243), 36 air litres/min (28190)

Norms: IEC 601-1 - Class II Type B. Made in Italy





**C €** 0476



#### STANDARD ACCESSORIES

Bottle 1 I - autoclavable at 120°C Silicone tubing set Suction catheter User manual (GB, IT, FR, DE, ES)

AC/DC universal adapter Anti-bacterial filter Cable to recharge batteries from car

- 28206 MINI ASPEED BATTERY PRO metal case 30 l/min High vacuum portable medical device for professional surgical aspiration.
- it can operate at 12 V (car) power supply, rechargeable batteries or directly by mains supply
- its two cylinders electro-compressor ensures high performances and long life
- up to 45 min. of autonomy with fully charged battery
- with 99% antibacterial hydrophobic filter
- equipped with autoclavable jar with safety valve, disposable suction liner and carrying case.
- 25480 SILICONE TUBE 6x12 mm roll of 30 m
- 28254 ADAPTOR FOR CATHETER
- 28255 HYDROPHOBIC 99% BACTERIAL FILTER
- 28258 AUTOCLAVABLE JAR 1000 ml (with cover) liner inside

  Output

  Disposable suction
- 28259 DISPOSABLE SUCTION LINER

autoclavable jar

#### TECHNICAL SPECIFICATIONS MINI ASPEED

Operating Voltage: 100-240 V 50/60 Hz AC - 14 V DC 4.28 A Size: 370x100x240 mm Weight: 5.8 kg (include kit)

Max suction: - 0.85 bar

Suction power: 30 air litres/min. Sound level: 65 db

Norms: MDD 93/42/ECC (class IIa - annex IX)

IEC 60601-1, UNI ENISO 10079-1

Made in Italy



Autoclavable jar 1000 cc with safety valve Silicone tubing set Ø 6x12 mm

Disposable suction liner Sterile cannula

Anti-bacterial hydrophobic filter Multivoltage battery charger Cigarette lighter power cord. Shoulder carrying bag User manual (GB and IT)



# SUPERVEGA SUCTION ASPIRATOR ON TROLLEY



• 28191 SUPER VEGA on trolley - suction 2x2 I jar • 28192 SUPER VEGA on trolley - suction 2x2 I jar with footswitch Continuously adjustable vacuum, with indicator. Silicone connection tube. 2 jars 2 litres, made of sterilizable polycarbonate (autoclavable at 120°C). Working time: 120 min ON, 60 min. OFF. Suction power: 40 air litres/min.

Steel painted frame, fitted with 5 star base. Norms CEI 62-5 (IEC 601-1) - Class II - Type B

- 28239 HYDROPHOBIC 99% BACTERIAL FILTER 25482 SILICONE TUBE 8x14 mm roll of 30 m

#### TECHNICAL SPECIFICATIONS

Size: 32x30xh 90 cm Weight 6.2 kg Operating voltage: 220-230 V - 50/60 Hz; other on request

Power consumption: 110 VA Maximum suction: -0.80 bar (600 mm Hg)

Flow: 40 air litres/minute Operating cycle: continuous Norms CEI 62-5 (IEC 601-1) - **( 6** 93/42 EEC

User manual (GB, FR, DE, IT, ES) Made in Italy



# VEGA SUCTION UNITS, HIGH VACUUM, LOW AND HIGH FLOW



#### **VEGA SUCTION UNITS**

A line of stylish, compact and reliable aspirators for small surgery. Silent, high flow and maintenance - free pumps allow long product life and durability.

Recommended for nasal aspiration, oral aspiration, tracheal aspiration of body liquids (mucus, catarrh or blood) in adults or children. Equipped with vacuum regulator continuously adjustable, vacuum indicator, unbreakable 1,000 ml or 2,000 ml bottle, autoclavable at 121°C, with safety float control valve to prevent overflow. Optional bottle autoclavable at 134°C. Manufactured in electric and thermal insulated plastic body.

Autoclavable and disposable collection system: In addition to standard autoclavable jar is available a disposable collection system composed by a rigid reusable container and a polyethylene disposable liner with cover, hermetically sealed, and hydrophobic, antireflux, bacterial filter operating as an

28211 28213





STANDARD ACCESSORIES

Autoclavable jar (1 or 2 l) with overflow valve system

6 languages user manual (GB, FR, IT, DE, ES, PT) 28229

Antibacterial and hydrophobic filter Set of silicone tubes 6x10 mm Conical connector for probes

**TECHNICAL SPECIFICATIONS 28209 VEGA UNO** 28210 VEGA 28211 SUPERVEGA 220-230 V - 50/60 Hz 220-230 V - 50/60 Hz Operating Voltage: 220-230 V - 50/60 Hz 110 V - 60 Hz (on request) 110 V - 60 Hz (on request) or 110 V - 60 Hz Power consumption: 184 W 184 W 106 W 1.000 ml 1.000 ml 1,000 ml or 2,000 ml Bottle capacity: Flow (air litres/min): 15 l/min 16 l/min 40 l/min Max suction: -0.75 bar (563 mm/Hg) -0.75 bar (563mm/Hg) -0.80 bar (600mm/Hg) Operating cycle: continuous continuous continuous 25x19x16.5 cm Size: 35x21x18 cm 35x21x18 cm Weight: 2.2 kg 2.5 kg 3.6 kg 93/42/ECC 93/42/ECC 93/42/ECC Norms:

GIMA code	VEGA SUCTION ASPIRATOR	Operating power	Flow
28209	Vega Uno	220-230 V - 50/60 Hz	15 l/m
28210	Vega	220-230 V - 50/60 Hz	16 l/m
28211	Super Vega 1l	220-230 V - 50/60 Hz	40 l/m
28212	Super Vega 2l	220-230 V - 50/60 Hz	40 l/m
28189	Super Vega 1l	110 V - 60 Hz	40 l/m



******	28227
	28272 28273
GIMA code	SPARE ACCESSORIES FOR VEGA AND TOBI LINE
28229	Hydrophobic, 99% antibacterial filter
28226	121°C autoclavable jar 1 l with cover and overflow system
28236	121°C autoclavable jar 2 I with cover and overflow system
28227	Cover and overflow valve system for 28226 and 28236
28185	134°C autoclavable jar 1 l with cover and overflow system
28186	
28184	Cover and overflow valve system for 28185 and 28186
28271	Disposable liner 1 l (cover + bag)
28270	Container for disposable liner 1 l
28268	
28273	Disposable liner 2 l (cover + bag)
28269	Disposable liner 2 I (cover + bag) - box of 50
28272	
25468	Silicone tube 6x10 mm - roll of 30 m
28252	Adaptor to connect catheter to silicone tube
	Suction catheter - see at page 43
28213	Trolley for Vega and Super Vega (not for Vega Uno)
28276	Vacuum indicator for Vega and Super Vega (not for Vega Uno)



#### ASPEED PROFESSIONAL SURGICAL ASPIRATORS

Piston-type continuous cycle electric aspirators give high performance and great durability. Equipped with a protective thermal cut-out relay. They require no maintenance or lubrication. A motor-protector cap totally prevents aspirated

GIMA code	ASPEED ASPIRATORS	Power	Pump	Case
28245	Aspeed 15 I	230 V	single	metal
	Aspeed 22 I	230 V	double	metal
	Aspeed 22 I	110 V	double	metal
28280	Aspeed 2 15 I	230 V	single	plastic
28281	Aspeed 2 22 I	230 V	double	plastic

Case material:

Noise level:

28222

liquids or secretions from reaching and damaging the vacuum pump. Ideal for clinical use. Made in Italy.

GIMA code	ACCESSORIES AND SPARES FOR ASPEED
28255 28258 28259 25480 28254 28261	Hydrophobic 99% bacterial filter Autoclavable jar 1l with cover Disposable suction liner Silicone tube 6x12 mm - roll of 30 m Adaptor to connect catheter to silicone tube Adaptor kit to use jar 1l (28258) with ASPEED manufactured before 2007

Suction power: 30 l/n

Max suction: -0.80 ba

#### STANDARD ACCESSORIES

Autoclavable policarbonate jar 1,000 cc Disposable suction liner 1 l 99% Antibacterial hydrophobic filter Sterile disposable cannula Sterile manual flow regulator Set of atoxic sterilizable silicone tubes Power Cable

with safety valve (overflow protection) User Manual GB, FR, IT, DE, ES

**ASPEED ASPEED 2** 28244 28245/6\* 28280 28281 230 V-50 Hz-230 V - 50/60 Hz Operating voltage: 110-60 Hz other voltage on request Bottle capacity: 1 I High vacuum: low flow low flow low flow high flow Air flow: 15 l/min 22 l/min 15 l/min 22 l/min Adjustable vacuum level: 0÷ -0.85 bar (0÷ -85 kPa) 3.5 kg 3.2 kg Weight: 4.5 kg 2.5 kg

65 dBA

-plastic-

55 dBA

55 dBA

Suction power: 18 l/m

Max suction: -0.75 bar

**TECHNICAL SPECIFICATIONS** 



# SUCTION ASPIRATORS HIGH VACUUM, LOW AND HIGH FLOW

-metal

55 dBA

• 28222 TOBI - suction aspirator 220-230 V - 50/60 Hz

• 28224 SUPER TOBI - suction aspirator 220-230 V - 50/60 Hz

Portable suction aspirators, ideal for tracheotomy and small surgery. Vacuum continuously adjustable with vacuum indicator. Have unbreakable 1,000 ml standard bottle (2,000 ml optional) autoclavable at 120°C with safety float control valve to prevent overflow.

Silicone connection tube.

ABS plastic case. Made in Italy

Silicone tube 6x10 mm (see page 159)

Adaptor for catheter (code 28252)

STANDARD A	ACCESSORIES	
	Tobi	Super Tobi
Bottle 1,000 ml with cover	1	1
Antibacterial Filter	1	1
Suction catheter	1	1
Silicon Tube set	1	1
User manual GB, FR, IT, DE, ES	1	1



28222 Tobi 28224Super Tobi 220-230 V - 50/60 Hz 220-230 V - 50/60 Hz Operating voltage: 106 W 184 W Power consumption: 1,000 ml 1.000 ml Bottle capacity: 18 l/min 40 l/min Flow (air litres/min): -0.75 bar (563mm/Hg) -0.80 bar (600mm/Hg) Max suction: Working time: minutes 20 ON / 40 OFF 120 ON / 60 OFF Size (cm): 37x22xh 21 cm 37x22xh 21 cm Weight: 3.5 kg 5.25 kg IEC 601-1 IEC 601-1 Norms:

HIGH VACUUM HIGH FLOW

# HIGH VACUUM, HIGH FLOW HOSPITAL SUCTION ASPIRATOR





Clinic Plus and Hospi Plus with foot switch and electronic flow direction regulator

New innovative range of high vacuum, high flow aspirator ideal for hospitals. Pump piston type, lubrication and maintenance free. Supplied with hydrophobic 99% bacterial filter, vacuum gauge for control of vacuum and 2 autoclavable jars (2 or 4 litres) made in makrolon with 200/400 ml graduation and double security valve. Available on request 2 or 3 litre disposable liners. Range includes version with foot

#### **TECHNICAL SPECIFICATIONS**

93/42 EEC. Made in Italy

Hospi plus Clinic plus 110 V or 230 V - 50/60 Hz Operating voltage: 230 V - 50/60 Hz - 110 V on request Maximum suction: - 0.90 bar (675 mmHg) - 0,90 bar (675 mmHg) Operating cycle: continuous continuous 90 l/min 60 l/min 300 VA 230 VA CEI 62-5 (IEC 601-1) CEI 62-5 (IEC 601-1)



switch and flow direction regulator, 110 and 230 V. Four antistatic castors, two of which with brake, allow a perfect mobility. User manual in GB, FR, IT, ES, DE. See spare accessories at page 159, 166. Made in Italy.

GIMA code	CLINIC PLUS / HOSPI PLUS	Jar	Power	Foot switch	Flow direction diverter*
	CLINIC PLUS aspirator	2x2 l	220-230 V	-	-
28196	CLINIC PLUS aspirator	2x4 l	220-230 V	-	-
	<b>CLINIC PLUS aspirator</b>	2x4 l	220-230 V	yes	yes
28200	<b>HOSPI PLUS aspirator</b>	2x2 l	220-230 V	-	-
	<b>HOSPI PLUS aspirator</b>	2x2 l	110 V	-	-
28201	<b>HOSPI PLUS aspirator</b>	2x4 l	220-230 V	-	-
28203	<b>HOSPI PLUS aspirator</b>	2x2 l	220-230 V	yes	yes
28204	<b>HOSPI PLUS aspirator</b>	2x4 l	220-230 V	yes	yes

\*Allow to direct suctioned liquids to any of the 2 jars

# MAXI ASPEED HIGH FLOW ASPIRATOR FOR HOSPITAL USE





93/42 EEC. Made in Italy



#### **TECHNICAL SPECIFICATIONS**

Operating voltage: 230 V - 50/60 Hz. Available on request 110 V - 60 Hz

60 or 90 l/min Air flow: Operating cycle: continuous Adjustable vacuum level: 0-0.90 bar (0-90 kPa) Size: 470x580x560 mm

15 kg (60 l), 17 kg (90 l) Weight: MDD class:

#### MAXI ASPEED SURGICAL ASPIRATORS

Surgical aspirators for aspiration of body liquids in operating theatres and hospitals.

#### Easy to carry

Equipped with 4 antistatic wheels (2 with brake) and carrying telescopic handle.

#### Developed to run continuously

Made in highly heat resistant, electrically insulated plastic material in conformity with latest European safety standards. Vacuum regulator with BAR/PSI vacuometer and automatic flow direction regulator to easily switch from a jar to the other. Supplied with 2 autoclavable polycarbonate jars with safety valve (overflow protection), set of atoxic sterilizable silicone tubes, 99% antibacterial hydrophobic filters (2) and multilanguage manual (GB, FR, IT, DE, ES). Made in Italy.

GIMA code	MAXI ASPEED	Jar	Power	Foot switch	Flow direction regulator
28285	Maxi Aspeed 60 l	2x2	230 V	-	yes
28286	Maxi Aspeed 60 l	2x2	230 V	yes	yes
28288	Maxi Aspeed 60 l	2x4	230 V	yes	yes
28289	Maxi Aspeed 90 l	2x2	230 V	-	yes
28291	Maxi Aspeed 90 l	2x4	230 V	-	yes
28292	Maxi Aspeed 90 l	2x4	230 V	yes	yes
ACCESSORIES					

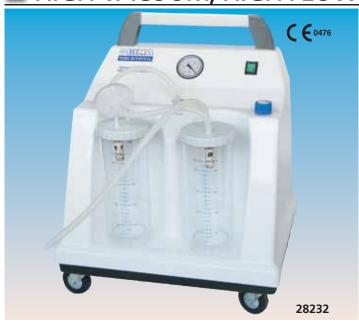
28294 Autoclavable jar 2 l with safety valve 28295 Autoclavable jar 4 l with safety valve 28297 Hydrophobic 99% antibacterial filter 25482 Silicone tube - 8x14 mm - roll of 30m



Flow: Power:

Norms:

# HIGH VACUUM, HIGH FLOW HOSPITAL SUCTION ASPIRATOR



Ideal for hospital, these suction aspirators are manufactured in ABS. Four antistatic castors, two of which with brakes, to allow perfect mobility. Vacuum gauge for the control of vacuum (1 bar). 2 or 4 litre jar made of autoclavable makrolon, with 200/400 ml graduation. Each jar with double security valve. Pump piston type, lubrication and maintenance free. With anti bacterial filter. Available model with footswitch and other operating voltage (110 V).

User manual in GB, FR, IT, ES, DE. Made in Italy.

GIMA code	TOBI CLINIC / HOSPITAL	Jar	Power	Foot switch
28231	TOBI CLINIC - suction aspirator	2x2l	220-230 V	-
28214	TOBI CLINIC - suction aspirator	2x2l	220-230 V	yes
28215	TOBI CLINIC - suction aspirator	2x4l	220-230 V	-
28216	TOBI CLINIC - suction aspirator	2x4l	220-230 V	yes
28232	TOBI HOSPITAL - suction aspirator	2x2l	220-230 V	-
28202	TOBI HOSPITAL - suction aspirator	2x2l	220-230 V	yes
28233	TOBI HOSPITAL - suction aspirator	2x4l	220-230 V	-
28234	TOBI HOSPITAL - suction aspirator	2x4l	220-230 V	yes
28235	TOBI HOSPITAL - suction aspirator	2x2l	110 V	_

#### TECHNICAL SPECIFICATIONS

	Hospital (28202-28232/3/4/5)	Clinic (28214/5/6, 28231)
Size:	55x45xh 65 cm	46x42xh 60 cm
Weight:	20 kg	13 kg
Operating voltage:	110 V or 230 V - 50/60 Hz	110 V or 230 V - 50/60 Hz
Maximum suction:	- 0.90 bar (675 mm/Hg)	- 0.90 bar (675 mm/Hg)
Operating cycle:	continuous	continuous
Flow:	90 l/min	60 l/min
Norms:	CEI 62-5 (IEC 601-1)	CEI 62-5 (IEC 601-1)
	93/42 EEC.	93/42 EEC.







GIMA code	ACCESSORIES FOR CLINIC/HOSPITAL, CLINIC PLUS, HOSPI PLUS	To be used with
28237 28239	Hydrophobic, 99% bacterial filter Hydrophobic, 99% bacterial filter	Hospital/Hospi plus Clinic/Supervega Trolley
28236 28227 28228 28223 28186 28184 28187	121°C autoclavable jar 2l with overflow system Cover 2l with overflow valve system 121°C autoclavable jar 4l with overflow system Cover 4l with overflow valve system 134°C autoclavable jar 2l with overflow system Cover 2l with overflow valve system 134°C autoclavable jar 5l with overflow system	28236 All 4 I aspirators 28228 All 2 I aspirators 28186
28272 28273 28274 28275		All 2 I aspirators 28272 Clinic/Hospital/ Hospital plus 2 I 28274
25482 28253 28276 28277	Silicone tube 8x14 - roll of 30 m Adapter to connect catheter to silicone tube Suction catheter see at page 43 Vacuum indicator Ø 50 mm Vacuum indicator Ø 60 mm	Clinic/Hospital 25482 28253 Clinic Clinic plus/Hospi Plus Hospital
28265 28266 28267	Bottom base Bottom base Bottom base	Clinic plus/Hospi Plus Clinic Hospital



## CLINIC PLUS SUCTION 2x2 l jar 230V

Code: 28194

Category: Hospital suction pumps aspirators

Unit of sale: 1 pc.

Minimum order: 1

Type: Medical device

Class: II A

NSIS: 590729

CND: Z120105

EAN13: 8023279281941

**Description:** CLINIC PLUS Basic

Autoclavable Jars: 2x2 l

• Footswitch: NO

• Flow direction diverter (Allows to direct suctioned liquids to any of the 2 jars): NO

Designed for professional aspiration of bodily fluids, tissues or bones of patients during or after surgery.

Oiless and maintenance free piston type pumps provide high performances. Excellent suction capacities and max vacuum built up within a few seconds.

Available with vacuum gauge and autoclavable jars made in makrolon with 200 ml (2 l jar) or 500 ml (4 or 5 l jars) graduation and 2-3 litres Flovac jars with disposable liners.

Wide range of versions with different features

- 60 l/m (Clinic Plus) or 90 l/m (Hospi Plus) flow rate
- -2,4 or 5 l jars
- MPR system for versatility
- footswitch and flow direction diverter

High standards of safety in overflow protection system

Double security valve integrated in the jar and hydrophobic filter (all models), safety trap bottle (only MPR models).

MPR (Multi Purpose Rail) models

This system enhances the versatility for easy and quick exchange of different accessories, with no need for tools.

Equipped with five connections for rings of various diameters to fit jars of different sizes and types (2l, 3l, 5l), cannula holders and safety trap bottle.

Main applications: EMERGENCY DEPT. / GYNAECOLOGY / OPERATING THEATRE / GENERAL SURGERY / NEUROSURGERY / DENTAL PRACTICE / OBSTETRICS

Size: 460 x 850 x 420 mm

Weight: 20 kg Made in Italy.

**Technical Specifications:** Operating voltage: 230 V - 50/60 Hz



Maximum suction: - 0,90 bar (675 mmHg)

**Operating cycle: continuous** 

Flow: 60 l/min Power: 230 VA Noise level: 51.7 dBA

Norms: CEI 62-5 (IEC 601-1); 93/42 EEC

Standard accessories: 121°C autoclavable jar with overflow valve system: 2x2 l

Rings to accommodate 5 l jars: NO Safety Trap Bottle (220 ml): NO

Antibacterial & Hydrophobic Filter (single-patient): 1 Autoclavable silicone tubes ø 8x14 mm length 150 cm: 1

Conical Connector ø 10-11-12mm: 1

Air suction inlet: 1

Footswitch with intermittent or continuous operation: NO Change-Over System from jar to jar by soft-touch keys: NO

Power Cord with Schuko plug: 1

Multilingual manual: GB, FR, IT, ES, DE, GR, PL, RO



# SPARE FILTER for Clinic, SuperVega trolley - connector 11 mm

Code: 28239

Category: Filtres

Unit of sale: 1 pc.

Minimum order: 1

Type: Medical device

Class: II A

NSIS: 1281843

CND: A0680

EAN13: 8023279282399

Description: Hydrophobic, antibacterial filter

Compatible with: SuperVega on trolley, Clinic, Clinic Plus



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

Gessate, 7 February 2012

#### **CONFORMITY OF GIMA PRODUCTS**

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

GIMA declares that all medical devices illustrated on

#### **GIMA INTERNATIONAL CATALOGUE**

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

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

as below:

- A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).
- B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

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

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10164 - A 2018-10-01 Reg. Number Valid From

2012-10-15 2018-10-01 First issue date Last change date

2021-10-14 29 Valid Until IAF Sector

#### Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

# GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

**Chief Operating Officer** Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

#### Kiwa Cermet Italia S.p.A. Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl

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E-mail: info@kiwacermet.it



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GIMA S.p.A.

**Certified Sites** 







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Reg. Number 10164 - M Valid From 2018-10-01

First issue date 2012-10-15 Last change date 2018-10-01

Valid until 2021-10-14

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

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

Chief Operating Officer Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A. Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl

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## Registered Headquarters

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