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ORDIN DE PLATA NR.: 1411                                TIP.DOC. 1 :
                                DATA EMITERII:17 iunie 2022 :
=====:
PLATITI: 2500-00                                LEI: Doua Mii Cinci Sute lei 00 ban :
i :
:
=====:
PLATITOR: (R) "BIOSISTEM                                CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L.                                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau                                :MOLDMD2X329:
=====:
BENEFICIAR (R) Centrul pen                                CONTUL DE PLATI/CODUL IBAN :
tru achizitii publice central MD23TRPCCC518430B01859AA :
izate in sanatate                                CODUL FISCAL :1016601000212 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
Ministerul Finantelor - Trezoreria de Stat                                :TREZMD2X :
=====:
DESTINATIA PLATII:/Pl02/2500,00 Pentru g: TIPUL TRANSFERULUI :
arantia pentru oferta la procedura de ac: NORMAL/URGENT :N:
hizi?ie publica nr. ocds-b3wdpl-MD-1651: :
847965407 din 18.06.2022 :
:
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:
=====:
                                CODUL TRANZACTIEI:101: :
DATA PRIMIRII:17/06/2022 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONducator:Web Poiata Vitalie :
MIIGYwYJKoZiHvcNAQcCoIIGVDCCB1ACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAAACBGwggRSMIIDUKADAgECAhNHAACjbilrgFksQ0G4AAAAAKNuMA0GCSqG:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFULXUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowZ8xZCzAJBgNVBAYTAk1EMRAw:
YDVQqQIEwdNb2xkb3ZhMREwDwYDVQqQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZiHvcNAQcCoIIGWDCCB1QCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAAACBHAWggRSMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNMA0GCSqG:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFULXUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQqQIEwdNb2xkb3ZhMREwDwYDVQqQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
:
L.S. (semnatura electronica) :
CONducator: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMnatura PRESTATORUL L.S. :
:
MOTIVUL REFUZULUI : L.S. :
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Digitally signed by Poiata Vitalie
Date: 2022.06.17 16:58:03 EEST
Reason: MoldSign Signature
Location: Moldova





BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

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

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

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

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

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

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

L. Svirepova
semnătura

MD 0101250





I.P. "AGENȚIA 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



EB 0358735

Lista fondatorilor Biosistem-mld SRL

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

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2210514**

din
OT **03.06.2022**

1. Destinația / Назначение

Pentru participarea la proceduri de achiziții publice

2. Date despre contribuabil / Информация о налогоплательщике

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

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

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

4. Valabil până la / Действителен до 18.06.2022

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

**Şef DDF Rîșcani
a DGDF**

Funcția/Dолжность

L.Ş/ М.П.

Executor: **Claudia GOJAN**

Numele şi prenumele/Фамилия и имя

Tel.(022)823102



Semnatura/Подпись

Ana STOICOV

Numele şi prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 03.06.2022 ora 11:51:41
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)

SITUAȚIILE FINANCIARE
pentru perioada 01.01.2021 - 31.12.2021

Entitatea: BIOSISTEM MLD S.R.L.
Cod CUIO: 40717392
Cod IDNO: 1010600028048

Sediul:
MD:
Raionul(municipiul): 106, DDF RISCANI
Cod CUATM: 0150, SEC.RISCANI
Strada: SECTORUL RISCANI STR.Albisoara nr.16 bl.1 of.7

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: +37322808719
WEB:
E-mail: zmii13@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

BILANȚUL

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care:	021		
	2.1. concesiuni, licențe și mărci			
	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		
	4. Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	2793637	3559998
	din care:	081		
	3.1. clădiri			
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	2791637	3533108
	3.4. mijloace de transport	084		

A.	3.5. inventar și mobilier	085		26890
	3.6. alte mijloace fixe	086	2000	
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120		1162136
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2793637	4722134
	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:			
	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			
	1. Creanțe comerciale pe termen lung	170		
	2. Creanțe ale părților afiliate pe termen lung	180		
	inclusiv: creanțe aferente intereselor de participare	181		
	3. Alte creanțe pe termen lung	190		
	4. 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	2793637	4722134
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	51978	5346
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	7221203	9147976
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	7273181	9153322
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	3912218	2182471
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	74631	208171
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350	2	
	7. Alte active circulante	360	5756117	1608597
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	9742968	3999239
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care:			
	2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		

	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	3942779	9861933
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	20958928	23014494
	TOTAL ACTIVE (rd.230 + rd.420)	430	23752565	27736628
	P A S I V			
C.	CAPITAL PROPRIU			
	I. Capital social și neînregistrat			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	()	()
	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	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	20060126	16230339
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	10403995
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	20060126	26634334
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	20065526	26639734
D.	DATORII PE TERMEN LUNG			
	1. 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		
	3. Datorii comerciale pe termen lung	650		
	4. 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			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	din care:	721		
	2.1. împrumuturi din emisiunea de obligațiuni			
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	3252667	343711
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	188105	355528
	6. Datorii față de personal	760	50	350
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	187676	150263
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	58541	247042
	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	3687039	1096894
F.	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	840		
	3. Provizioane pentru impozite	850		
	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	23752565	27736628

SITUAȚIA DE PROFIT ȘI PIERDERE

de la pînă la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	25963175	38680547
din care:			
venituri din vânzarea produselor și mărfurilor	011	25044358	37724557
venituri din prestarea serviciilor și executarea lucrărilor	012	918817	951393
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016		4597
Costul vânzărilor, total	020	15186814	24434231
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	15186814	24433364
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 vânzărilor	026		867
Profit brut (pierdere brută) (rd.010 - rd.020)	030	10776361	14246316
Alte venituri din activitatea operațională	040	247603	5189
Cheltuieli de distribuire	050	19740	6076
Cheltuieli administrative	060	1259776	1788732
Alte cheltuieli din activitatea operațională	070	640169	1870642
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	9104279	10586055

Venituri financiare, total	090	519239	1517765
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	25612	30619
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	493627	1487146
Cheltuieli financiare, total	100	597528	249562
din care:			
cheltuieli privind dobânzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	597528	249562
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-78289	1268203
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-78289	1268203
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	9025990	11854258
Cheltuieli privind impozitul pe venit	170	1051159	1450263
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	7974831	10403995

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la pînă la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
	4. Capital retras	040	()	()	()	()
	5. 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				
III.	Rezerve					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130				
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X			
	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 + rd.180)	190				

SITUAȚIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	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 vânzarea 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 sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

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Расписка 2

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2021

Дата предоставления: 29.03.2022

Временная метка отчёта зарегистрированного в Информационной Системе НБС : 29.03.2022 17:25:45

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](#)

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Расписка

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2021

Дата предоставления: 29.03.2022

Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 29.03.2022 14:51:06



AGENȚIA DE MEDIU

ENVIRONMENTAL AGENCY

MD-2005 mun.Chișinău, str. Albișoara, 38
Tel. (022) 820-770, Email: am@am.gov.md

CONFIRMARE

privind înregistrarea în „Lista producătorilor” de produse
supuse reglementărilor de responsabilitate extinsă a producătorului
(echipamente electrice și electronice)

În scopul plasării pe piață a produselor de echipamente electrice și electronice, în conformitate cu prevederile art. 12 alin. (5) și alin. (14) lit. b) din Legea nr. 209 din 29.07.2016 privind deșeurile, și punctele 46 – 50 din Regulamentul privind deșeurile de echipamente electrice și electronice, aprobat prin Hotărîrea Guvernului nr. 212 din 07.03.2018, se emite numărul de înregistrare

MD2021-10-EEE-005

pentru BIOSISTEM MLD, IDNO: 1010600028048, cu adresa juridică: mun. Chișinău, str. Albișoara 16/1, ap. 1.

Numărul de înregistrare este valabil începînd cu data de 02.11.2021 pînă la data de 02.11.2024.

Director adjunct interimar
Gavril GÎLCA



Saver One[®]

Complete **AEDs** range to **save lives**.



**life is a breath,
...keep it safe with us**

www.amiitalia.com

THE IMPORTANCE OF AEDs TO BEAT/WIN SCA

Sudden cardiac arrest is unpredictable; it can happen anywhere, anytime, at any age and without any warning. For each minute that passes by the probability of survival drops of 7/10%. Time is crucial in these situations and using an AED might be the only effective action.

EACH 2 SECONDS SUDDEN CARDIAC ARREST **CLAIMS 1 LIFE !!** TO ANYONE, ANYWHERE

A life- threatening condition that can be reversible just thanks to a timely defibrillation.



THE KEY IS TO UNABLE AVAILABILITY AND EASY ACCESS TO AEDs



SPORT FACILITIES:

Regardless of the discipline performed, AED provision should be mandatory for professional, semi-professional and amateur sports.



COMMUNITIES:

A lack of confidence in using an AED and the inability to locate a nearby device is a missed opportunity to save lives! Governments should strongly advocate for public access defibrillation programs; every citizen could be trained and then become a potential first responder to a SCA.

WORKPLACES:



As the chances of surviving a cardiac arrest are increased if the emergency treatment is provided promptly, AED provision is highly recommended to any work places that aims to an health and safe enviroment.



HOSPITALS:

ERC guidelines says “ ...staff should be trained to enable achievement of the goal of providing the first shock within 3 minutes of collapse anywhere in the hospital”



SCHOOLS:

AEDs are easy to use: by following the simple and clear voice prompts bystanders can perform all the crucial steps that can save lives. Furthermore several studies indicate that students without any CPR/AED training can use an AED as instructed.

Sa^{ver}One®





Sudden Cardiac Arrest can happen anytime, anywhere and without warning.
The person affected has only few precious minutes left for a chance of survival.
YOUR FIRST AID COULD BE SOMEBODY'S LAST CHANCE

SAVER ONE AEDs are designed for a public access use and licensed to administer fast and safe rescues.
Highly-effective and user-friendly for any lay rescuer, even without minimal training.

SAVER ONE Semi and Fully Automatic defibrillators are two dependable members of our AED family.
The Fully Automatic administers a defibrillating shock (when appropriate) with no shock button for the user to press whilst the Semi-Automatic administers a shock at the press of a button.

Choose the best portable AED that's right for you to save lives everywhere in any public circumstance (home, office, school, hotel, airport, train, beach, gym, pool, disco, etc.) and before EMS team arrives.

Automated testing to vouch daily functionality

A **new look** complete with all pictograms which light up to guide rescuers step by step

More alternatives for recording and transfer data: **internal memory**, removable **card**, **USB**

Slight yet solid with **long-lasting battery options** to ensure the best portability in any circumstance

Biphasic technology **up to 360J energy**

Unique features combined with available configurations give rise to exclusive devices



SEMI-AUTOMATIC two buttons

Meet AHA/ERC 2017 Guidelines



Maintenance-Free: Automatically performs daily, monthly and six-month extensive self-checks of all main components: battery, internal electronics, energy charge and disarm, shock and ECG calibration systems. Daily testing data are stored by the device as text file (named AED1LOG) easily readable by any computer.
AED runs further tests after each battery insertion as well as every time the device is turned on.
A visual cue (green/red status indicator) provides effective alert to users whether AED is in working order and ready for a rescue.

Service Mini-Screen: The mini LCD screen always displays a battery gauge with its residual percentage charge, error codes in faulty conditions, text prompts in accordance with audible voice instructions helpful in noisy and chaotic environments.

INFO button: The "i" button provides valuable device/battery technical information and enable to change the language

CPR Coaching: More instructive voice and text prompts guide user through rescue. A built-in metronome assist responder during the CPR, providing audio cues for the appropriate number and rate of chest compressions.

Adult/Child capability: after connecting pads to the patient, flashing icons on the keyboard display which pads are in use (adult/pediatric). Devices senses when pediatric pads are installed and adjusts to use the appropriate lower energy level (50J).

DEFIBRILLATOR

Operation:	Semi-Automatic Version Fully Automatic Version
Energies:	Standard max 200J or Power max 360J
Waveform:	Adaptive BTE (biphasic truncated exponential) conforming to patient chest's impedance
Protocols:	Various adult shock protocols available on request
Factory default:	Adult Standard escalating 150, 200, 200J Adult Power escalating 200, 250, 360J Pediatric (Standard or Power) 50J fixed
Charging time:	≤ 9 seconds with a new and fully charged battery depleted battery will result in a longer charging time
Analysis time:	IEC/EN 60601-2-4 from 4 to 15 seconds
Impedance:	20-200 ohms
Sensitivity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 97%
Specificity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 99%
Controls:	3 buttons for Semi-Automatic: ON/OFF, Shock "i" info button 2 buttons for Automatic: ON/OFF, "i" info button
Flashing Icons:	"connects pads to patient" "adult/child" informing on pads type use "don't touch patient" warning to stay clear "touch patient" informing it's safe to touch
Indicators:	Status LED indicator informing on device condition Battery gauge with remaining capacity rate Audible alerts and text display with service alarms
Upgradeable:	through a USB cable or memory card



FULLY AUTOMATIC one button

MODEL NUMBERS

Code SVO-B0001: Semi-Automatic Standard Version at 200J
Code SVO-B0002: Semi-Automatic Power Version at 360J

Code SVO-B0847: Fully Automatic Standard Version at 200J
Code SVO-B0848: Fully Automatic Power Version at 360J

CONFIGURATION OPTIONS (Box Contents)

Conf-Norm:	Standard Basic Configuration (adult pads, disposable battery, carrying case)
Conf-Rech:	Rechargeable Configuration (adult pads, accumulator, charger station, carrying case)

BATTERY OPTIONS

Type:	Li-SOCI2 Disposable, code SAV-C0903
Autonomy:	300 complete rescue cycles (shocks at 200J and CPR) or 200 complete rescue cycles (shocks at 200J and CPR) or 35 hours ECG Monitoring for a new and fully charged battery (*)
Shelf-Life:	when stored in original packaging 5 years (*)
Battery-Life:	4 years once installed to AED, assuming one battery insertion test and daily self-test but without switching AED on (*)

Type:	Li-ion Accumulator, code SAV-C0011
Recharging time:	2,5 hours with the charger station code SAV-C0014 (*) (recommended to charge every 4 months at least)
Autonomy:	250 shocks at 200J or 150 shocks at 360j or 21 hours in ECG Monitoring for a new fully charged accumulator (*)
Battery-Life:	2 years or 300 charging cycles (*)

PADS OPTIONS

Type:	Disposable, pre-gelled and self-adhesive
Adult:	Code SAV-C0846, for patient >8 years or >25 kg
Pediatric:	Code SAV-C0016, for patient <8 years or <25 kg
Cable lenght:	120 cm
Shelf-Life:	30 months

EVENT RECORDING

Internal memory:	up to 6 continuous hours of ECG and rescue events.
Memory capacity:	6 hours of audio, ECG and events
Optional memory:	Removable SD card, Length of storage depends on card capacity: a 2GB card records up to 100 hours
Data recording:	"AED1LOG" text file with detailed self-test activity "AEDFILES" with complete recorded events
Event review:	"Saver View Express" data manager software

PHYSICAL

Size:	26,5 x 21,5 x 7,5 cm 1,95 kg with disposable battery 2,10 kg with rechargeable battery
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ENVIRONMENTAL

Operating temperature:	0°C to 55°C (32°F TO 131°F)
Storing/Shipping temperature:	-40°C to 70°C (-40°F TO 158°F) without battery
Humidity:	10% to 95% relative humidity non condensing
Sealing (IP Protection):	IEC/EN 60529 class IP54; splash proof, dust protected
Shock/Drop Abuse Endurance:	IEC/EN 60601-1 clause 21; 1 meter drop, impact, force, rough handling, mobile tolerance
Electrostatic Discharge:	IEC/EN 61000-4-2
Electromagnetic Compatibility:	IEC/EN 60601-1-2 Emission, Immunity
Electrical Protection:	IEC/EN 60601-1 class I type BF
Directive	
93/42/CEE and 2007/47/CE:	Class IIb

(*)Temperature at 20°C Humidity 45% non-condensing

6 YEARS WARRANTY

Manufactured in Italy



Saver One D

the AED goes beyond

SAVER ONE D is a rugged, small and lightweight **AED** with **ECG Monitoring** capability. Totally reliable for trained users featuring advanced capacities to help improve lifesaving outcomes.

THE RIGHT CHOICE FOR HARSH, OUTDOOR OR MOBILE USE

While in AED mode, it allows the user to view the ECG and everything needed to know about the patient and ongoing rescue treatment on a very large (12x8 cm) full-color interactive display. Additionally the SAVER ONE D can be switched in a ECG Monitoring mode, to allow for watch over the rhythm and heart rate while using defibrillation pads or standard ECG electrodes connected to a separate cable.

Great graphical interface combined with instructive voice prompts to guide rescuers

Functionality ensured by **automatic daily self-test**

Slight yet solid with **long-lasting battery options** to ensure the best portability in any circumstance

More alternatives for recording and transfer data: **internal memory**, removable **card**, **USB**, and **IrDA Port** optional with Print Configuration

Biphasic technology **up to 360J energy**

Unique features combined with available configurations give rise to exclusive devices

Meet AHA/ERC 2017 Guidelines



AED ECG Monitoring

Saver One D

Maintenance-Free: Automatically performs daily, monthly and six-month extensive self-checks of all main components: battery, internal electronics, energy charge and disarm, shock and ECG calibration systems. Daily testing data are stored by the device as text file (named AED1LOG) easily readable by any computer. AED runs further tests after each battery insertion as well as every time the device is turned on. A visual cue (green/red status indicator) provides effective alert to users whether AED is in working order and ready for a rescue.

Service Mini-Screen: In standby the mini LCD screen displays a check mark confirming AED is ready for use and a battery gauge informing about the residual charge. Error codes will appear in faulty conditions.

Helpful Menu: 3 buttons for navigating the software menu to set up device at user leisure: adjust the local date or time, adapt the screen or volume to ambient lights and noises, exclude the microphone while recording events, select a different language, print out the ECG files or simply get information on device and battery.

CPR Coaching: More instructive voice and text prompts guide user through rescue. A built-in metronome assist responder during the CPR providing audio cues for the appropriate number and rate of chest compressions.

Adult / Child Capability: Can be used on patients of any age with Adult or Pediatric proper electrodes. Device senses when Pediatric pads are installed and automatically adjusts to use a more appropriate lower energy level (50J).

Monitoring section menu: a new section has been introduced for the management of technical and physiological alarms and signals, according to IEC/EN 60601-2-27: patient loss, high or low heart rate, audio and visual signal for detection of a shockable rhythm so that the operator can switch/active one of the available modes to deliver the shock (using the appropriate pads); scaling of the ECG trace on the display (gain x2 or /2) reset of the audio or visual alarms..

DEFIBRILLATOR

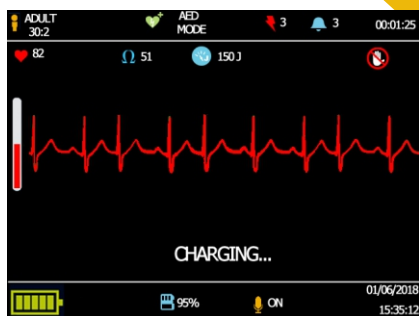
Operation:	AED Semi-Automatic ECG Monitoring capability
Energies:	Standard max 200J or Power max 360J
Waveform:	Adaptive BTE (biphasic truncated exponential) conforming to patient chest's impedance
AED Protocols:	Various adult shock protocols available on request
Factory default:	Adult Standard escalating 150, 200, 200J Adult Power escalating 200, 250, 360J Pediatric (Standard or Power) 50J fixed
Charging time:	≤ 9 seconds with a new and fully charged battery depleted battery will result in a longer charging time
Analysis time:	IEC/EN 60601-2-4 from 4 to 15 seconds
Impedance:	20-200 ohms
Sensitivity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 97%
Specificity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 99%
Controls:	2 buttons: ON/OFF, shock button, and 3 buttons to surf the menu.
Indicators:	Status LED indicator informing on device condition Battery Gauge with remaining capacity rate Audible alerts and text display with service alarms
Upgradeable:	through a USB cable or memory card

ECG MONITORING

Operations:	Through defibrillation pads or standard ECG electrodes attached to a separate 2-Lead patient monitoring reusable cable SAV-C0017
ECG size:	Manual setting through the menu
Heart Rate:	30-300 bpm
Sweep Speed:	25 mm/sec
Standard:	IEC/EN 60601-2-27 less then the points 202.6.2.101; 201.12.1.101.12,13; 208.6.6.2.101 not performed for the intended use of the device, as it is not intended for environments such as operating theaters or intensive care units
Display:	5,7" TFT color, 640 x 480 pixel

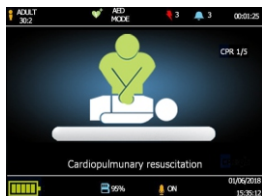
5.7" TFT Color Display

the most detailed and comprehensive screen provides valuable information to rescuers running text and interactive graphics combined with voice messages



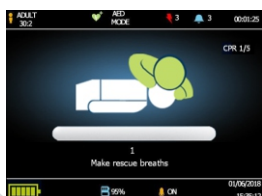
ABOUT DEVICE:

a **battery gauge** with residual capacity the indicator of **available memory** for recording a notice if the **microphone** is active or OFF the local **date and time**



ABOUT RESCUE:

the adult or child **protocol in use** the **modality in use** (AED or ECG) the **fibrillation and shock counts** the elapsed **rescue time** the **heart rate** (bpm) the **impedance** (ohms) the **ECG waveform** a **touch/not touch** pictogram a **charging bar graph** if device charges the **energy level** to be delivered (joule) a **CPR bar graph** as countdown a **CPR cycles count**



BATTERY OPTIONS

Type:	Li-SOCI2 Disposable, code SAV-C0903
Autonomy:	250 complete rescue cycles (shocks at 200J and CPR) or 160 complete rescue cycles (shocks at 360J and CPR) or 24 hours ECG Monitoring for a new and fully charged battery (*) when stored in original packaging 5 years (*)
Shelf-Life:	
Battery-Life:	4 years once installed to AED, assuming one battery insertion test and daily self-test but without switching AED on (*)
Type:	Li-ion Accumulator, code SAV-C0011
Recharging time:	2,5 hours with the charger station code SAV-C0014 (*) (recommended to charge every 4 months at least)
Autonomy:	200 shocks at 200J or 110 shocks at 360J or 14 hours in ECG Monitoring for a new fully charged accumulator (*)
Battery-Life:	2 years or 300 charging cycles (*)

PADS OPTIONS

Type:	Disposable, pre-gelled and self-adhesive
Adult:	Code SAV-C0846, for patient >8 years or >25 kg
Pediatric:	Code SAV-C0016, for patient <8 years or <25 kg
Cable lenght:	120 cm
Shelf-Life:	30 months

EVENT RECORDING

Internal memory:	up to 6 continuous hours of ECG and rescue events.
Memory capacity:	6 hours of audio, ECG and events
Optional memory:	Removable SD card, Length of storage depends on card capacity: a 2GB card records up to 100 hours
Data recording:	"AED1LOG" text file with detailed self-test activity "AEDFILES" with complete recorded events
Event review:	"Saver View Express" data manager software

PHYSICAL

Size:	26,5 x 21,5 x 7,5 cm 2,30 kg with disposable battery 2,45 kg with rechargeable battery
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ENVIRONMENTAL

Operating temperature:	0°C to 55°C (32°F TO 131°F)
Storing/Shipping temperature:	-40°C to 70°C (-40°F TO 158°F) without battery
Humidity:	10% to 95% relative humidity non condensing
Sealing (IP Protection):	IEC/EN 60529 class IP54; splash proof, dust protected
Shock/Drop Abuse Endurance:	IEC/EN 60601-1 clause 21; 1 meter drop, impact, force, rough handling, mobile tolerance
Electrostatic Discharge:	IEC/EN 61000-4-2
Electromagnetic Compatibility:	IEC/EN 60601-1-2 Emission, Immunity
Electrical Protection:	IEC/EN 60601-1 class I type BF
Directive	
93/42/CEE and 2007/47/CE:	Class IIb

MODEL NUMBERS

Code SVD-B004:	Standard Version with maximum energy at 200J
Code SVD-B005:	Power Version with maximum energy at 360J

CONFIGURATION OPTIONS (Box Contents)

Conf-Norm:	Standard Basic Configuration (adult pads, disposable battery, carrying case)
Conf-Rech:	Rechargeable Configuration (adult pads, accumulator, charging station, carrying case)
Conf-Print:	Print Ready Configuration (adult pads, disposable battery, carrying case, IrDA port and thermal printer)
Conf-Rech/Print:	Rechargeable & Print Ready Configuration (adult pads, accumulator, charger station, carrying case, IrDA port and thermal printer)

(*) Temperature at 20°C Humidity 45% non-condensing

6 YEARS WARRANTY

Manufactured in Italy



IMQ mark for
Safety & Quality



0051

Saver One P[®]

the handy PRO AED

SAVER ONE P is a tough, small and lightweight Defibrillator easy to carry and use anywhere and able to act as an **AED** or a Manual Defibrillator or a Basic Cardiac Monitoring device.

HIGHLY FLEXIBLE AND VERSATILE WITH ADVANCED CAPABILITIES

AED per default, reliable for any BLS rescuer, can be easily switched in a Manual Defibrillator giving to ALS responders the best decision-making control for a manual shock timing or an electric cardioversion (synchronised shock).

To meet ALS professionals, SAVER ONE P has been designed with all advanced key features to make fast and effective defibrillation everywhere and in any circumstance, even the hardest and has been equipped with a new widely manageable software program which gives users the total control of device to suit their needs. Practical and flexible with Advanced PBLIS feature enabling healthcare providers to use the 15:2 CV ratio when performing a Pediatric Basic Life Support, as required by Guidelines if more than one rescuer with a duty to respond.

Supreme graphical user interface and new tools to have **total control** of the defibrillator

Biphasic **escalating energy** from 50 to 360J

Slight yet solid with long-lasting battery options to ensure the **best outdoor and mobile use**

Functionality guaranteed by daily self-test

Wider connectivity with removable card, USB and IrDA Port optional with Print Configuration

Unique features combined with available configurations give rise to exclusive devices



Meet AHA/ERC 2017 Guidelines

Saver One P[®]

Maintenance-Free: Automatically performs daily, monthly and six-month extensive self-checks of all main components: battery, internal electronics, energy charge and disarm, shock and ECG calibration systems. Daily testing data are stored by the device as text file (named AED1LOG) easily readable by any computer.

AED runs further tests after each battery insertion and every time device is turned on.

A visual cue (green/red status indicator) provides effective alert to users whether AED is in working order and ready for a rescue.

Service Mini-Screen: In standby the mini LCD screen displays a check mark confirming AED is ready for use and a battery gauge informing about the residual charge. Will run error codes in faulty conditions.

Entirely Discretionary: 6 push-buttons allowing users to get the total control of defibrillator while in use: select the best modality, Manual Synchronous or Asynchronous or simply AED, to treat SCA according to events, take decision for shock anytime by choosing the right energy level to be delivered at each shock and get the device charged and ready to shock whenever needed or even disarm it in case defibrillation is not more required.

After shocks, the heart rhythm rate can be watched over using the same defibrillation pads or, in case of longer monitoring, by connecting standard ECG electrodes to a separate optional reusable cable.

Each step is conducted with the appropriate running features selected and set up in the device software by users.

Adult / Child Capability: Can be used on patients of any age with Adult or Pediatric proper electrodes. Device senses when Pediatric pads are installed and automatically adjusts to use a more appropriate lower energy level (50J).

Monitoring section menu: a new section has been introduced for the management of technical and physiological alarms and signals, according to IEC/EN 60601-2-27: patient loss, high or low heart rate, audio and visual signal for detection of a shockable rhythm so that the operator can switch/active one of the available modes to deliver the shock (using the appropriate pads); scaling of the ECG trace on the display (gain x2 or /2) reset of the audio or visual alarms..

AED
ECG Monitoring
MANUAL Override

DEFIBRILLATOR

Operation:	AED Semi-Automatic (default) ECG Monitoring Manual Asynchronous or Synchronous (used to convert atrial or ventricular tachyarrhythmias)
Energies:	Standard max 200J or Power max 360J
Waveform:	Adaptive BTE (biphasic truncated exponential) conforming to patient chest's impedance
Energy type:	Escalating from 50 to 360J
AED Protocols:	Adult Standard escalating 150, 200, 200J Adult Power escalating 200, 250, 360J Pediatric (Standard or Power) 50J fixed (AED adult shock protocols can be customized)
Manual Protocol:	Selected by users from 50 to 360J. For electric cardioversion (in Synchronous mode) the shock is synchronised to occur with the R wave of the ECG.
Energy Display:	Screen provides the energy to deliver both in Manual mode or AED mode
Charging time:	≤ 9 seconds with a new and fully charged battery depleted battery will result in a longer charging time
Analysis time:	IEC/EN 60601-2-4 from 4 to 15 seconds
Impedance:	20-200 ohms
Sensitivity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 97%
Specificity:	IEC/EN 60601-2-4 (AHADB, MITDB source), 99%
Controls:	2 buttons: ON/OFF, shock button; 3 buttons: to surf the menu; 3 buttons: select energy, charge, disarm the device
Indicators:	Status LED indicator informing on device condition Battery Gauge with remaining capacity rate Audible alerts and text display with service alarms through a USB cable or memory card
Upgradeable:	

ECG MONITORING

Operations:	Through defibrillation pads or standard ECG electrodes attached to a separate 2-Lead patient monitoring reusable cable SAV-C0017
ECG size:	Manual setting through the menu
Heart Rate:	30-300 bpm
Sweep Speed:	25 mm/sec
Standard:	IEC/EN 60601-2-27 less than the points 202.6.2.101; 201.12.1.101.12.13; 208.6.6.2.101 not performed for the intended use of the device, as it is not intended for environments such as operating theaters or intensive care units
Display:	5,7" TFT color, 640 x 480 pixel

BATTERY OPTIONS

Type:	Li-SOCI2 Disposable, code SAV-C0903
Autonomy:	250 complete rescue cycles (shocks at 200J and CPR) or 160 complete rescue cycles (shocks at 360J and CPR) or 24 hours ECG Monitoring for a new and fully charged battery (*)
Shelf-Life:	when stored in original packaging 5 years (*)
Battery-Life:	4 years once installed to AED, assuming one battery insertion test and daily self-test but without switching AED on (*)
Type:	Li-ion Accumulator, code SAV-C0011
Recharging time:	2,5 hours with the charger station code SAV-C0014 (*) (recommended to charge every 4 months at least)
Autonomy:	200 shocks at 200J or 110 shocks at 360J or 14 hours in ECG Monitoring for a new fully charged accumulator (*)
Battery-Life:	2 years or 300 charging cycles (*)

PADS OPTIONS

Type:	Disposable, pre-gelled and self-adhesive
Adult:	Code SAV-C0846, for patient >8 years or >25 kg
Pediatric:	Code SAV-C0016, for patient <8 years or <25 kg
Cable length:	120 cm
Shelf-Life:	30 months

EVENT RECORDING

Internal memory:	up to 6 continuous hours of ECG and rescue events.
Memory capacity:	6 hours of audio, ECG and events
Optional memory:	Removable SD card, Length of storage depends on card capacity: a 2GB card records up to 100 hours
Data recording:	"AED1LOG" text file with detailed self-test activity "AEDFILES" with complete recorded events
Event review:	"Saver View Express" data manager software

PHYSICAL

Size:	26,5 x 21,5 x 7,5 cm 2,30 kg with disposable battery 2,45 kg with rechargeable battery
-------	--

ENVIRONMENTAL

Operating temperature:	0°C to 55°C (32°F TO 131°F)
Storing/Shipping temperature:	-40°C to 70°C (-40°F TO 158°F) without battery
Humidity:	10% to 95% relative humidity non condensing
Sealing (IP Protection):	IEC/EN 60529 class IP54; splash proof, dust protected
Shock/Drop Abuse Endurance:	IEC/EN 60601-1 clause 21; 1 meter drop, impact, force, rough handling, mobile tolerance
Electrostatic Discharge:	IEC/EN 61000-4-2
Electromagnetic Compatibility:	IEC/EN 60601-1-2 Emission, Immunity
Electrical Protection:	IEC/EN 60601-1 class I type BF
Directive	
93/42/CEE and 2007/47/CE:	Class IIb

MODEL NUMBERS

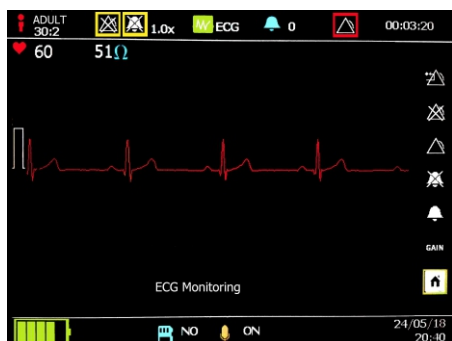
Code SVP-B0006:	Standard Version with maximum energy at 200J
Code SVP-B0007:	Power Version with maximum energy at 360J

CONFIGURATION OPTIONS (Box Contents)

Conf-Norm:	Standard Basic Configuration (adult pads, disposable battery, carrying case)
Conf-Rech:	Rechargeable Configuration (adult pads, accumulator, charger station, carrying case)
Conf-Print:	Print Ready Configuration (adult pads, disposable battery, carrying case, IrDA port and thermal printer)
Conf-Rech/Print:	Rechargeable & Print Ready Configuration (adult pads, accumulator, charger station, carrying case, IrDA port and thermal printer)

(*) Temperature at 20°C Humidity 45% non-condensing

5.7" TFT Color Display
the most detailed and comprehensive screen
provides valuable information to rescuers
running text and interactive graphics
combined with voice messages

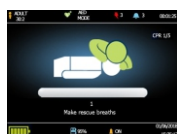
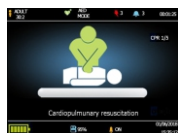


ABOUT DEVICE:

a **battery gauge** with residual capacity
the indicator of **available memory** for recording
a notice if the **microphone** is active or OFF
the local **date and time**, alarms.

ABOUT RESCUE:

the adult or child **protocol in use**
the **modality in use** (AED, ECG or Manual)
the **fibrillation and shock counts**
the elapsed **rescue time**
the **heart rate** (bpm)
the **impedance** (ohms)
the **energy level** to be delivered (joule)
a **touch/not touch** pictogram
the **ECG waveform**
the **R wave** detection in Manual Synchronous
a **charging bar graph** if device charges
a **CPR bar graph** and cycles countdown



6 YEARS WARRANTY

Manufactured in Italy

IMQ mark for Safety & Quality 0051

SAVER ONE AED Series supplies and accessories

Training Solutions



Saver One T code SVT-B0959

A smart and easy-to-use AED Trainer providing realistic training for many responders simultaneously.

Designed to meet needs of any instructor, it helps your responders learn to use defibrillators in simulated sudden cardiac arrest episodes for an extremely realistic training experience. A non-shocking unit that follows the 1, 2, 3-step operations of the Saver One defibrillator and guides responders, with voice prompts in various languages, from ECG analysis until shock and CPR. It is pre-configured with 10 realistic training scenarios manageable from distance with a wireless remote control and is equipped with a rechargeable battery which allows a 20 hours of continuous operating.



Both SAVER ONE T Versions come equipped with one set of adult reusable training pads, a remote control, an accumulator with its charger, a quick reference card, an user manual and a carrying case.

CPR Manikin

HALF- BODY TRAINING MANIKIN MAN-B0608/MAN-B1058

With acoustic indicator of the correct deepness of compression; a knob on the back with three different selection (adult-child-neutral) corresponding to 3 kinds of manikin resistance to compressions

Content:

- 1 CPR Simulator
- 1 User Manual & FAQ
- 6 Lungs & 2 Valves
- 1 Transport bag with MAT



BABY TRAINING TRAINING MANIKIN MAN-B1059/MAN-B1060

The most lifelike infant manikin suitable for performing correct infant CPR, performing realistic breathing and head tilt.



Content:

- 1 Practi-Baby
- 1 User manual
- 5 lungs and 2 valves
- 1 Transport bag

Fast Access Solution

NEW OUTDOOR CABINET:

- WITH ALARM
- WITH HEATING & ALARM (SAV-C1051)

Outdoor Wall Cabinet AMI ITALIA in polystyrene and ABS available with alarm or with heater & alarm
100% dust- and waterproof



NEW INDOOR CABINET:

- WITH ALARM (SAV-C0961)
- WITHOUT ALARM (SAV-C0912)

Indoor AMI ITALIA Wall Cabinet in strong metal, seamless look with or without audible alarm



10



WALL BRACKET (code SAV-C0911) & CARRYING CASE (code SAV-C0916)

Wall Mount Bracket in metal, designed for housing our AEDs in its carrying case.

Carrying case made of special shock proof and splashproof material, with adjustable shoulder strap and hook handle.



INDOOR CABINET: (code SAV-C1064)

Indoor Cabinet with customized video display

TOTEM STAND SUPPORT



To provide easy access and visibility to your AEDs for outdoor location.

SAV-C1062: Outdoor Metal Cabinet Yellow, With Heater And Alarm, Internal Light, Digital Display For Temperature.

SAV-C1063: Outdoor Metal Cabinet White and Green, With Heater And Alarm, Internal Light, Digital Display For Temperature

SAV-C1067: Column for Outdoor AED cabinet yellow SAV C1062

SAV-C1068: Column for Outdoor AED cabinet white and green SAV C1063

INDOOR CABINET: (code SAV-C1065 / C1066)

Indoor Cabinet Heart Shape Internal Cabinet with Alarm Colour White/Red (Batteries Not Included)



AED Wall Sign: (code SAV-C0997)

An AED Wall Sign hanging above a Wall Mount Bracket or Defibrillator Cabinet gives even greater visibility to the defibrillator.

ECG Monitoring & Data Management

2-Lead ECG Cable

(code SAV-C0017)

Suitable for SAVER ONE D and SAVER ONE P Defibrillators when used in ECG Monitoring mode. The alternative to pads in case of long-term monitoring to be connected to standard ECG electrodes.

8GB SD Card

(code SAV-C0907)

This removable card holds approximately 100 hours of events, ECG information and voice recording.

One card can hold data from multiple cases.

A flash data card reader enables data transfer from the card to a personal computer for use with the Saver View Express data management software.

Thermal Printer

(code SAV-C1070)

Works with SAVER ONE D and SAVER ONE P Defibrillators optioned with the Print Ready Configuration (Conf-Print).

Those are equipped with IrDA Port and therefore are able to communicate with this external thermal printer.

Data saved into device can be selected from the menu and print it out as ECG format complete with case details.



Simulator / Tester Smart Simulator S1

(code SSS-B0009)

This equipment can be used for a complete operating test of Saver One Defibrillators.

It comes with a dedicated cable to be plugged to any Saver One AED in order to let it run as it was a real lifesaving treatment.

Able to simulate several ECG rhythms (VF, VT, NSR, Asystole, etc.) and display the energy level discharged, up to 360J.

Saver View Express

(code SAV-C0019)

Saver View Express is a comprehensive data management tool for the most demanding professional allowing to view and manage on your PC patient data downloaded from defibrillators. With fully detailed data screen to record every aspect of the treatment, including response times, interventions, and rescuer observations.

Connecting Cable

(code SAV-C0158)

Spare connecting cable for Smart Simulator S1.

6 YEARS WARRANTY

Manufactured in Italy



IMQ mark for Safety & Quality



0051



IMQ mark for
Safety & Quality



North Italy Office
Viale Gran Sasso, 11
20131 Milano - Italy
Tel: +39.02.20509246
Fax: +39.02.29520839

South Italy Office & Production
Via Cupa Reginella, 15A
80010 Quarto - Italy
Tel: +39.081.8060574
Fax: +39.081.8764769

Headquarters production site:
A.M.I. International kft.
Kőzúzó u. 5/A 2000 Szentendre HU
Hungary
Tel. +3626302210

CERTIFICATO CE

Certificato n. 1104/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

A.M.I. ITALIA S.R.L.

80143 NAPOLI (NA) - VIA G. PORZIO CENTRO DIREZIONALE IS.G2 (ITA) - Italy

mantiene negli stabilimenti di:

A.M.I. INTERNATIONAL KFT - 2000 SZENTENDRE - ROZSA UTCA 16 (HUN) - Hungary

A.M.I. ITALIA SRL - 80010 QUARTO (NA) - VIA CUPA REGINELLA 15A (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Defibrillatore cardiaco esterno semiautomatico e manuale semiautomatico

Modd. SAVER ONE P; SAVER ONE D

Defibrillatore cardiaco esterno automatico e semiautomatico

Mod. SAVER ONE.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

10AI00006; 10AJ00117; COMEDCONMHDM110027747-01; 10EN00018;
10AO00009; DM17-0009799-01; DM17-0018806; DM17-0020656-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.

Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2008-02-18
Data di Aggiornamento: 2018-02-16
Sostituisce: 2017-11-20
Data Scadenza: 2023-02-15

IMQ

 **IMQ** 
ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

EC CERTIFICATE

Certificate No 1104/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

A.M.I. ITALIA S.R.L.

80143 NAPOLI (NA) - VIA G. PORZIO CENTRO DIREZIONALE IS.G2 (ITA) - Italy

manages in the factories of:

A.M.I. INTERNATIONAL KFT - 2000 SZENTENDRE - ROZSA UTCA 16 (HUN) - Hungary

A.M.I. ITALIA SRL - 80010 QUARTO (NA) - VIA CUPA REGINELLA 15A (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Semiautomatic and manual semiautomatic external cardiac defibrillator

Type ref. SAVER ONE P; SAVER ONE D

Automatic and semiautomatic external cardiac defibrillator

Type ref. SAVER ONE.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AI00006; 10AJ00117; COMEDCONMHDM110027747-01; 10EN00018;
10AO00009; DM17-0009799-01; DM17-0018806; DM17-0020656-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.

Notified Body notified to European Commission under number: 0051.

Date: 2008-02-18
Updated: 2018-02-16
Substitution Date: 2017-11-20
Expiry Date: 2023-02-15

IMQ



IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts



www.imq.it

CISQ is a member of



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

CERTIFICATO N. 9124.AMI2
CERTIFICATE N.

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

A.M.I. ITALIA S.R.L.

VIA G. PORZIO CENTRO DIREZIONALE IS.G2 - 80143 NAPOLI (NA)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA CUPA REGINELLA 15A - 80010 QUARTO (NA)

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

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione, immissione in commercio ed assistenza tecnica di defibrillatori cardiaci esterni e relativi accessori. Commercializzazione di dispositivi per il monitoraggio dei parametri fisiologici vitali
Design, production, placing on the market and technical assistance of external cardiac defibrillators and related accessories. Sales of monitoring devices of vital physiological parameters

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

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE	EMISSIONE CORRENTE	SCADENZA
	FIRST CERTIFICATION	CURRENT ISSUE	EXPIRY
	2002-05-31	• 2019-01-29	2022-03-19

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



SGQ N° 005 A

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

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



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

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



www.imq.it

CISQ is a member of



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

CERTIFICATO N. 9120.AMIT
CERTIFICATE N.

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

A.M.I. ITALIA S.R.L.

VIA G. PORZIO CENTRO DIREZIONALE IS.G2 - 80143 NAPOLI (NA)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA CUPA REGINELLA 15A - 80010 QUARTO (NA)

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

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione, immissione in commercio ed assistenza tecnica di defibrillatori cardiaci esterni e relativi accessori. Commercializzazione di dispositivi per il monitoraggio dei parametri fisiologici vitali
Design, production, placing on the market and technical assistance of external cardiac defibrillators and related accessories. Sales of monitoring devices of vital physiological parameters

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

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE	EMISSIONE CORRENTE	SCADENZA
	FIRST CERTIFICATION	CURRENT ISSUE	EXPIRY
	2004-09-08	2019-01-29	2022-03-19

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



IAF: 19, 29

SGQ N° 005 A

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

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



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

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



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

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

A.M.I. ITALIA S.R.L.

VIA CUPA REGINELLA 15A - 80010 QUARTO (NA)

has implemented and maintains a

Quality Management System

for the following scope:

Design, production, placing on the market and technical assistance of external cardiac defibrillators and related accessories. Sales of monitoring devices of vital physiological parameters

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

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: 2019 - 01 - 29

Expires on: 2022 - 03 - 19

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

Registration Number: IT - 37690



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
President of CISQ

IQNet Partners*:

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

VEGA SUCTION UNITS, HIGH VACUUM, LOW AND HIGH FLOW

CE 0476

HIGH VACUUM
HIGH FLOW

28211

28210

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 overflow valve. Made in Italy.

1 l polycarbonate autoclavable jar with overflow safety valve

28252
Adaptor to connect catheter to silicone tube

STANDARD ACCESSORIES

Autoclavable jar (1 or 2 l) with overflow valve system
Antibacterial and hydrophobic filter
Set of silicone tubes 6x10 mm
Conical connector for probes
6 languages user manual (GB, FR, IT, DE, ES, PT) **28229**



TECHNICAL SPECIFICATIONS

	28209 VEGA UNO	28210 VEGA	28211 SUPERVEGA
Operating Voltage:	220-230 V - 50/60 Hz 110 V - 60 Hz (on request)	220-230 V - 50/60 Hz 110 V - 60 Hz (on request)	220-230 V - 50/60 Hz or 110 V - 60 Hz
Power consumption:	184 W	184 W	106 W
Bottle capacity:	1,000 ml	1,000 ml	1,000 ml or 2,000 ml
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
Size:	25x19x16.5 cm	35x21x18 cm	35x21x18 cm
Weight:	2.2 kg	2.5 kg	3.6 kg
Norms:	93/42/ECC	93/42/ECC	93/42/ECC

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



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 l 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	134°C autoclavable jar 2 l with cover and overflow system
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	Disposable liner 1 l (cover + bag) - box of 50
28273	Disposable liner 2 l (cover + bag)
28269	Disposable liner 2 l (cover + bag) - box of 50
28272	Container for disposable liner 2 l Ø 13 cm top, 9.5 cm bottom
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)



GIMA

"SUPER-VEGA" SUCTION ASPIRATOR 1 liter jar

Code:	28211
Category:	Surgical aspirators and breast pump
Unit of sale:	1 pc.
Minimum order:	1
Type:	Medical device
Class:	II A
NSIS:	590729
CND:	Z120105
EAN13:	8023279282115



Description: SUPER VEGA 1 l SUCTION ASPIRATOR

Flow: 40 l/m

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 APEC® jar autoclavable at 143°C.

Manufactured in electric and thermal insulated plastic body.

Flovac® autoclavable jars and disposable collection system: in addition to standard autoclavable jar, a disposable collection system is available, composed by a rigid reusable jar, a polyethylene disposable liner with hermetically sealed cover and hydrophobic, antireflux, bacterial filter operating as an overflow valve.

Technical Specifications:	• Operating voltage:
	- 220-230 V / 50-60 Hz
	- 110-127 V - 60 Hz (on request)
	• Power consumption: 110 VA
	• Bottle capacity: 1000 ml
	• Flow (air litres/min): 40 l/min
	• Max suction: -0.80 bar (600 mmHg)
	• Operating cycle: continuous
	• Noise level: 60.5 dBA
	• Size: 35 x 21 x 18 cm
	• Weight: 3.6 kg
	• Norms: 93/42/ECC
	• Made in Italy

Standard accessories:	• Autoclavable jar with overflow valve system
	• Antibacterial and hydrophobic filter
	• Set of silicone tubes 6 x 10 mm
	• Conical connector for probes
	• 6 languages user manual (GB, FR, DE, IT, ES, PT)



GIMA

SPARE FILTER for codes 28190, 28209-12, 28220-25, 28243

Code:	28229
Category:	Filtres
Unit of sale:	1 pc.
Minimum order:	1
Type:	Medical device
Class:	II A
NSIS:	2080363
CND:	A0680
EAN13:	8023279282290
Description:	Hydrophobic antibacterial filter - spare



HIGH VACUUM, HIGH FLOW HOSPITAL SUCTION ASPIRATOR



Standard Clinic Plus and Hospi Plus



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

	Hospi plus	Clinic plus
Operating voltage:	110 V or 230 V - 50/60 Hz	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
Flow:	90 l/min	60 l/min
Power:	300 VA	230 VA
Norms:	CEI 62-5 (IEC 601-1)	CEI 62-5 (IEC 601-1)
	93/42 EEC. Made in Italy	93/42 EEC. Made in Italy



Size: 460x850x420 mm
Weight: 20 kg

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*
28194	CLINIC PLUS aspirator	2x2 l	220-230 V	-	-
28196	CLINIC PLUS aspirator	2x4 l	220-230 V	-	-
28198	CLINIC PLUS aspirator	2x4 l	220-230 V	yes	yes
28200	HOSPI PLUS aspirator	2x2 l	220-230 V	-	-
28199	HOSPI PLUS aspirator	2x2 l	110 V	-	-
28201	HOSPI PLUS aspirator	2x4 l	220-230 V	-	-
28203	HOSPI PLUS aspirator	2x2 l	220-230 V	yes	yes
28204	HOSPI PLUS aspirator	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



TECHNICAL SPECIFICATIONS

Operating voltage:	230 V - 50/60 Hz. Available on request 110 V - 60 Hz
Air flow:	60 or 90 l/min
Operating cycle:	continuous
Adjustable vacuum level:	0-0.90 bar (0-90 kPa)
Size:	470x580x560 mm
Weight:	15 kg (60 l), 17 kg (90 l)
MDD class:	Ila

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 multilingual 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 l	230 V	-	yes
28286	Maxi Aspeed 60 l	2x2 l	230 V	yes	yes
28288	Maxi Aspeed 60 l	2x4 l	230 V	yes	yes
28289	Maxi Aspeed 90 l	2x2 l	230 V	-	yes
28291	Maxi Aspeed 90 l	2x4 l	230 V	-	yes
28292	Maxi Aspeed 90 l	2x4 l	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





GIMA

CLINIC PLUS SUCTION 2x4 l jar 230V with footswitch, flow regulator

Code:	28198
Category:	Hospital suction pumps aspirators
Unit of sale:	1 pc.
Minimum order:	1
Type:	Medical device
Class:	II A
NSIS:	590729
CND:	Z120105
EAN13:	8023279281989

**Description:****CLINIC PLUS Full**

- Autoclavable Jars: 2x4 l
- Footswitch: YES
- Flow direction diverter (Allows to direct suctioned liquids to any of the 2 jars): YES

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

Oilless 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
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GIMA

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: 2x4 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: 1

Change-Over System from jar to jar by soft-touch keys: 1

Power Cord with Schuko plug: 1

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



GIMA

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



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

A handwritten signature in black ink, appearing to read 'N. Manzoni', with a stylized flourish at the end.



Reg. Number	10164 - A	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid Until	2021-10-14	IAF Sector	29

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
Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

GIMA S.p.A.

Registered Headquarters

- Via Grossi, 2 20121 Milano Italia

Certified Sites

- Via Marconi, 1 20060 Gessate (MI) Italia



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.

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40057 Granarolo dell'Emilia
(BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

GIMA S.p.A.

Registered Headquarters

- Via Grossi, 2 20121 Milano Italia

Certified Sites

- Via Marconi, 1 20060 Gessate (MI) Italia



SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 0041
PRS N° 089C