ORDIN DE PLATA NR.: 824 TIP.DOC. 1

DATA EMITERII:13 iulie 2021

PLATITI: 5000-00 LEI: Cinci Mii lei 00 bani

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.
CONTUL DE PLATI/CODUL IBAN
MD95ML000000002251429243
CODUL FISCAL :1010600028048 /

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

BENEFICIAR (R) Centrul pen tru achizitii publice izate in sanatate
CONTUL DE PLATI/CODUL IBAN
MD23TRPCCC518430B01859AA
CODUL FISCAL :1016601000212 /

PRESTATORUL BENEFICIAR
Ministerul Finantelor - Trezoreria de Stat
CODUL BANCII:
:TREZMD2X :

DESTINATIA PLATII:/P102/5000,00 Pentru g: arantia pentru oferta la procedura de ac: hizi?ie publica nr. ocds-b3wdp1-MD-16234: 02942659 din 13.07.2021

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:101:
DATA PRIMIRII:13/07/2021
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

L.S.

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

Digitally signed by Poiata Vitalie
Date: 2021.07.12 18:51:43 EEST
Reason: MoldSign Signature
Location: Moldova

MOTIVUL REFUZULUI L.S.

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

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

Data 14. IAN. 2016
Nr. 03/2 – 19/23

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

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

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

MD 0101250

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor 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 şi codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;

3 Acordarea asistenţei medicale de către instituţiile medico-sanitare private;

4 Comerţul cu ridicata al calculatoarelor, echipamentelor periferice şi software-ului;

5 Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul;

6 Consultaţii în domeniul sistemelor de calcul.

Capitalul social: **5400** lei.

Administrator: POIATA VITALIE,

Asociaţi:

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 şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840

Lazari Aliona

"AGENŢIA SERVICII PUBLICE" IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0358735

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

Lista fondatorilor Biosistem-mld SRL

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

Дата предоставления 11.05.2021 10:00:47

Anexe la SNC
"Prezentarea situațiilor financiare"
Aprobat de Ministerul Finanțelor
al Republicii Moldova

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2020 - 31.12.2020

Entitatea: BIOSISTEM MLD S.R.L.
Cod CUIÎO: 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: Dl (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

la

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul 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	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		
	4. Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	487	
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	2208593	2793637
	din care: 3.1. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	2204135	2791637
	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: 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	2209080	2793637
	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	54051	51978
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	5710647	7221203
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (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
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350	4	2
B.	7. Alte active circulante	360	1647908	5756117
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	6152127	9742968
	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	8911899	3942779
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	20828724	20958928
	TOTAL ACTIVE (rd.230 + rd.420)	430	23037804	23752565
	P A S I V			
	CAPITAL PROPRIU			
	I. Capital social și neînregistrat			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	( )	( )
	3. Capital nelnregistrat	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		
C.	**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	21021465	12085295
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	7974831
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	21021465	20060126
	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	21026865	20065526
	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care: 2.1. Împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: Împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
D.	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		
	din care: 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
	4. Datorii față de părțile afiliate curente	740		
E.	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			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	840		
F.	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	23037804	23752565

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 vînzări, total	010	27319617	25963175
din care: venituri din vînzarea produselor și mărfurilor	011	26856566	25044358
venituri din prestarea serviciilor și executarea lucrărilor	012	463051	918817
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	15186814
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	15672962	15186814
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	10776361
Alte venituri din activitatea operațională	040	28586	247603
Cheltuieli de distribuire	050	16306	19740
Cheltuieli administrative	060	964136	1259776
Alte cheltuieli din activitatea operațională	070	417394	640169
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10277405	9104279

Venituri financiare, total	090	490609	519239
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093		25612
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	490609	493627
Cheltuieli financiare, total	100	686605	597528
din care: cheltuieli privind dobînzile	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	686605	597528
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-195996	-78289
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	-195996	-78289
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	10081409	9025990
Cheltuieli privind impozitul pe venit	170	1178993	1051159
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	8902416	7974831

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				
IV.	**Profit (pierdere)**					
	1. Corecții ale rezultatelor anilor precedenți	120	X			
	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 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 sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Расписка 2

Респондент
Фискальный 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 Информационной Системе НБС : 11.05.2021 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.

Расписка

Респондент
Фискальный 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

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: str. Albișoara 16/1 of.7, or. Chișinău
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-1623402942659
din 21 iun 2021, 11:30 - 13 iul 2021, 11:30
din cadrul CAPCS

Declarație

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

- Va instala și 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 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).

_____Vitalie Poiata

L.Ş.

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 QUALITA'

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 ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

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

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 factory of:

A.M.I. INTERNATIONAL KFT - 2000 SZENTENDRE - KOZUZO u. 5/A (HUN) - Hungary

80010 QUARTO (NA) - VIA CUPA REGINELLA 15A (ITA) - Italy

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

External cardiac defibrillator

Type ref. as to Document "Defibrillatore Cardiaco Esterno" Rev.0 dated 2018/11/09; valid only if provided with IMQ mark.

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; DM18-0023720-01; DM18-0032037-01; DM19-0034531-01.

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:	2019-02-22
Substitution Date:	2018-11-15
Expiry Date:	2023-02-15

IMQ

A.M.I. Italia S.r.l.
Via Cupa Reginella, 15/a - 80010 QUARTO
Tel. +39 081 8060574 - Fax +39 081 8764769
www.amiitalia.com info@amiitalia.com
P.I. e C.F. : 07291540636

CATEGORIA di prodotto:

Defibrillatore Cardiaco Esterno

	Variante	Modalità Operativa	Energia MAX erogabile	REF
GeoSaver P (Capostipite)	Con display TFT LCD e miniLCD	Semiautomatico/Manuale	200J	SGP-B0994
	Con display TFT LCD e miniLCD	Semiautomatico/Manuale	360J	SGP-B0995

	Variante	Modalità Operativa	Energia MAX erogabile	REF
SaverOne P	Con display TFT LCD e miniLCD	Semiautomatico/Manuale	200J	S1P-B0986
	Con display TFT LCD e miniLCD	Semiautomatico/Manuale	360J	S1P-B0987

	Variante	Modalità Operativa	Energia MAX erogabile	REF
GeoSaver D	Con display TFT LCD e miniLCD	Semiautomatico	200J	SGD-B0992
	Con display TFT LCD e miniLCD	Semiautomatico	360J	SGD-B0993

	Variante	Modalità Operativa	Energia MAX erogabile	REF
SaverOne D	Con display TFT LCD e miniLCD	Semiautomatico	200J	S1D-B0984
	Con display TFT LCD e miniLCD	Semiautomatico	360J	S1D-B0985

	Variante	Modalità Operativa	Energia MAX erogabile	REF
GeoSaver	Con miniLCD graphic	Semiautomatico	200J	SGS-B0988
	Con miniLCD graphic	Semiautomatico	360J	SGS-B0989
	Con miniLCD graphic	Automatico	200J	SGA-B0990
	Con miniLCD graphic	Automatico	360J	SGA-B0991

	Variante	Modalità Operativa	Energia MAX erogabile	REF
SaverOne	**Senza** miniLCD graphic	Semiautomatico	200J	S1B-B0980
	Senza miniLCD graphic	Semiautomatico	360J	S1B-B0981
	Con miniLCD graphic	Semiautomatico	200J	S1S-B0978
	Con miniLCD graphic	Semiautomatico	360J	S1S-B0979
	Con miniLCD graphic	Automatico	200J	S1A-B0982
	Con miniLCD graphic	Automatico	360J	S1A-B0983

	Variante	Modalità Operativa	Energia MAX erogabile	REF
SaverOne P	Con display TFT LCD e miniLCD	Semiautomatico/Manuale	200J	SVP-B0006
	Con display TFT LCD e miniLCD	Semiautomatico/Manuale	360J	SVP-B0007

	Variante	Modalità Operativa	Energia MAX erogabile	REF
SaverOne D	Con display TFT LCD e miniLCD	Semiautomatico	200J	SVD-B0004
	Con display TFT LCD e miniLCD	Semiautomatico	360J	SVD-B0005

	Variante	Modalità Operativa	Energia MAX erogabile	REF
SaverOne	**Senza** miniLCD graphic	Semiautomatico	200J	SVO-B0918
	Senza miniLCD graphic	Semiautomatico	360J	SVO-B0919
	Con miniLCD graphic	Semiautomatico	200J	SVO-B0001
	Con miniLCD graphic	Semiautomatico	360J	SVO-B0002
	Con miniLCD graphic	Automatico	200J	SVO-B0847
	Con miniLCD graphic	Automatico	360J	SVO-B0848

Rev.0 del 2018-11-09

2019-02-22

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

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

CSQ
www.imq.it

CERTIFICATO N. / *CERTIFICATE N.* 9120.AMIT

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 *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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

IAF: 19, 29

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

IMQ
Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
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 direcly 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.

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

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
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CERTIFICATO N. / *CERTIFICATE N.* 9124.AMI2

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 *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-05-31	2019-01-29	2022-03-19

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

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

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


SaverOne
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 pubblic 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.

SaverOne

Confsport Italia

SaverOne®
everywhere for life

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

SaverOne®

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 enviroments.

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

BATTERY OPTIONS

Type:	Li-SOCl2 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

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

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)

6 YEARS WARRANTY

Manufactured in Italy

IMQ mark for Safety & Quality

CE 0051

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 law 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

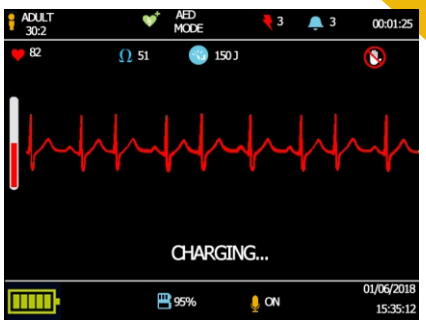
Operation:	AED Semi-Automatic ECG Monitoring capability
Energies:	Standard max 200J or Power max 360J
Waveform:	Adaptive BTE (biphasic truncated exponential) conforming to patient chest's impedance
AED Protocols:	Various adult shock protocols available on request
Factory default:	Adult Standard escalating 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-SOCl2 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 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

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

CE 0051

SaverOne 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 PBLS 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

SaverOne P®

AED
ECG Monitoring
MANUAL Override

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 law 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 (default) ECG Monitoring Manual Asynchronous or Synchronous (used to convert atrial or ventricular tachyarrthythimias)
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
Upgradeable:	through a USB cable or memory card

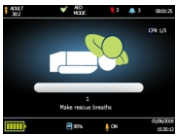
ECG MONITORING

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, 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

BATTERY OPTIONS

Type:	Li-SOCl2 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 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

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

6 YEARS WARRANTY

Manufactured in Italy

IMQ mark for Safety & Quality

CE 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 gifferent 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 Trasport 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 Trasport 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

WALL BRACKET (code SAV-C0911) & CARRING 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.

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.

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.

6 YEARS WARRANTY

Manufactured in Italy

IMQ mark for Safety & Quality

CE 0051

AMI ITALIA
MEDICAL DEVICES

AMI INTERNATIONAL
MEDICAL DEVICE

IMQ mark for
Safety & Quality

CE
0051

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20131 Milano - Italy
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Fax: +39.02.29520839

South Italy Office & Production
Via Cupa Reginella, 15A
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Tel: +39.081.8060574
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Kőzúzó u. 5/A 2000 Szentendre HU
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VERS. AMI 02-2019

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www.gimaitaly.com

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

Gessate, 7 February 2012

CONFORMITY OF GIMA PRODUCTS

According to the annex VII of the Council Directive 93/42/EEC

as amended by the European Directive 2007/47/EEC concerning medical devices

GIMA declares that all medical devices illustrated on

GIMA INTERNATIONAL CATALOGUE

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

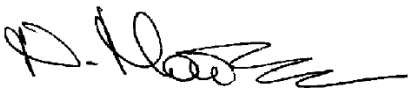
93/42/EEC AS AMENDED BY THE EUROPEAN DIRECTIVE 2007/47/EEC

as below:

A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).

B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

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



CERTIFICATE

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

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

CERTIFICATE

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

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

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SGQ N° 007A
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FSM N° 004I
PRS N° 089C

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

Size: 460x850x420 mm
Weight: 20 kg

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 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.

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) 93/42 EEC. Made in Italy	CEI 62-5 (IEC 601-1) 93/42 EEC. 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

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.

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:	IIa

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				

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.
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: 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**

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