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ORDIN DE PLATA NR.: 1500                                TIP.DOC. 1 :
                                DATA EMITERII:4 august 2022 :
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PLATITI: 5000-00                                LEI: Cinci Mii lei 00 bani :
:
:
=====
PLATITOR: (R) "BIOSISTEM                                CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L.                                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
:
:
=====
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. 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:/P102/5000,00 Pentru g: TIPUL TRANSFERULUI :
arantia pentru oferta la procedura de ac: NORMAL/URGENT :N:
hizi?ie publica nr. ocds-b3wdp1-MD-16566: :
77828975 din 05.08.2022 :
:
:
: L.S. :
=====
                                CODUL TRANZACTIEI:101: :
DATA PRIMIRII:04/08/2022 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
-----
CONDUCTOR:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCB1ACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB :
DQEHAAcCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq :
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4 :
DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA :
gYDVQQIEwdNb2xkb3ZHMREwDwYDVQQHEWhDaGlzaw5hdTEWMBQGA1UEChMNQm :
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGVDCCB1QCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3 :
DQEHAAcCBHawggRSMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG :
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X :
DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw :
YDVQQIEwdNb2xkb3ZHMREwDwYDVQQHEWhDaGlzaw5hdTEWMBQGA1UEChMNQm :
L.S. (semnatura electronica) :
CONDUCTOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
MOTIVUL REFUZULUI : L.S. :
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BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

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

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

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

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent 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*

A. Svirid
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.
№ **A2214024**

din
от **26.07.2022**

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 10.08.2022

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

Șef DDF Rîșcani
a DGDF
Funcția/Dолжность
L.Ș/ М.П.
Executor: **Claudia GOJAN**
Numele și prenumele/Фамилия и имя
Tel.(022)823102



Ana STOICOV

Numele și prenumele/Фамилия и имя

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	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		
	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		
Dobînzii 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		
Dobînzii 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		

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

Сохранить

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 Hotărârea 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 începând cu data de 02.11.2021 până la data de 02.11.2024.

Director adjunct interimar
Gavril GÎLCA

AXIS AX 135

EO GAS STERILIZER



135 liter EO Gas Sterilizer



KORDON

Tıp Sağlık Araç ve Gereçleri

Manufacturer: KORDON TIP SAGLIK ARAC GERECLERI

PROJ. MUH. ITH.SAN. VE TIC.LTD.STI.

10006/1 No:43 A.O.S.B CIGLI IZMIR TURKIYE

www.kordontip.com * info@kordontip.com

Tel: +90232.348.60.60 * Fax: +90232.348.60.90

<https://www.youtube.com/channel/UCJffYtHhdi-Zps3ncSUGU9w>



Axis offers the latest technology in gas diffusion sterilization systems. The products to be sterilized are placed in the Liner Bag together with the EO Gas Cartridge, Dosimeter, Humidity Chip and sealed with a tie or a sealing machine. All information on the device is provided to be displayed on the color monitor. All stages such as resistance, fan, vacuum, conditioning, sterilization, ventilation and so on can be easily followed, and visual and auditory warnings are given in case of any malfunction. EO is used in healthcare facilities to sterilize critical items (and sometimes semi-critical items) that are sensitive to moisture or heat and cannot be sterilized by steam or other sterilization methods. Therefore, a wide variety of materials, especially polymeric components commonly used in medical devices, can be sterilized with EO. The cabin is automatically kept under permanent vacuum in all stages (conditioning-sterilization-ventilation) and user safety is ensured.

AX-135 Features

Capacity	135 liter
Display	Dixell Controller
Internal Dimensions (WxDxL)	35x110x35 cm
External Dimensions (WxDxL)	37x122x41 cm
Weight	41 kg
Power	400W
Amperage	2A
Voltage	110-220 VAC
Working Temperature	30-59°C
Outer Material	Decorative Inox
Inner Material	Stainless Steel
Safety	Manual Door Lock
Preconditioning	0-9 Hours
Sterilization	1-9 Hours
Aeration	0-9 Hours
Total Cycle Time	1-27 Hours
Liner Bag	47x130 cm
EO Cartridge	ARQ-11 / ARQ-5 / AR-11

- 100% EO and 100% Safe
- Vacuum type sealing and gasket pressure plate
- With negative pressure operation, measurement and safety system
- Sterilization and Ventilation in the same cabinet
- Microcomputer operating system
- 4 hour short program
- Practical and easy to use
- Pipe congestion warning system, works under permanent vacuum
- Cabin safety pressure measurement and instant monitoring
- Robust construction
- Use without failure risk, completely maintenance-free, full work
- Floor heating system
- Automatic door-lock system that does not require a mechanical handle
- In-bag humidity and temperature values can be seen online on the screen
- Integrated mobile humidity/temperature probe with calibration
- Ability to store past cycle reports in memory, when requested can be print from the internal printer again.
- MDR compliant, EN 61010-2-40, EN 61010-1, EN 60601-1-2 EMC, EN 60601-1, ISO 9001-13485 with Test and Quality Reports
- New software compatible with EN 14937 for validation studies
- Suitable for invasive sterilization

What can be sterilized with AX 135 EO Gas Sterilizer?

- Heat- sensitive equipment
- Assembled complex devices
- Catheters, stents, syringes, medical gloves,surgical threads
- Custom procedure packs
- Equipment with integrated electronics
- Multi-lumen tubing products
- Wound care dressings
- Plastic, metal, and rubber medical supplies
- Laparoscopic and endoscopic equipment
- Surgical instruments
- Surgical gowns and drapes
- Endoscopes, dental instruments
- Spices; thyme, mint
- Pharmaceutical capsules and boxes,brushes, face powders
- Old books and library applications
- Fabrics, leather, chemical fibers



Order from info@kordontip.com / sales@kordontip.com

Tel: +90232.348.60.60 * Fax:+90232.348.60.90



Axis EO Gas Sterilizers works with;
Axis EO Gas Cartridges (AR series)
and these are consists of;

- Liner bag and tie-wrap
- 100% Gas Cartridge of 11g or 5g
- Humidity Chip
- Dosimeter Indicator
- Dosimeter Tracking Form

OR

Axis EO Gas Sterilizers works with;
Axis Ampoule Sets (ARQ series)
and these are consists of;

- Liner bag and tie-wrap
- 100% Gas Ampoule of 11g or 5g
- Humidity Chip
- Dosimeter Indicator (optional)



The ends of the Axis ethylene oxide ampoules are sealed with hermetic sealing technique.

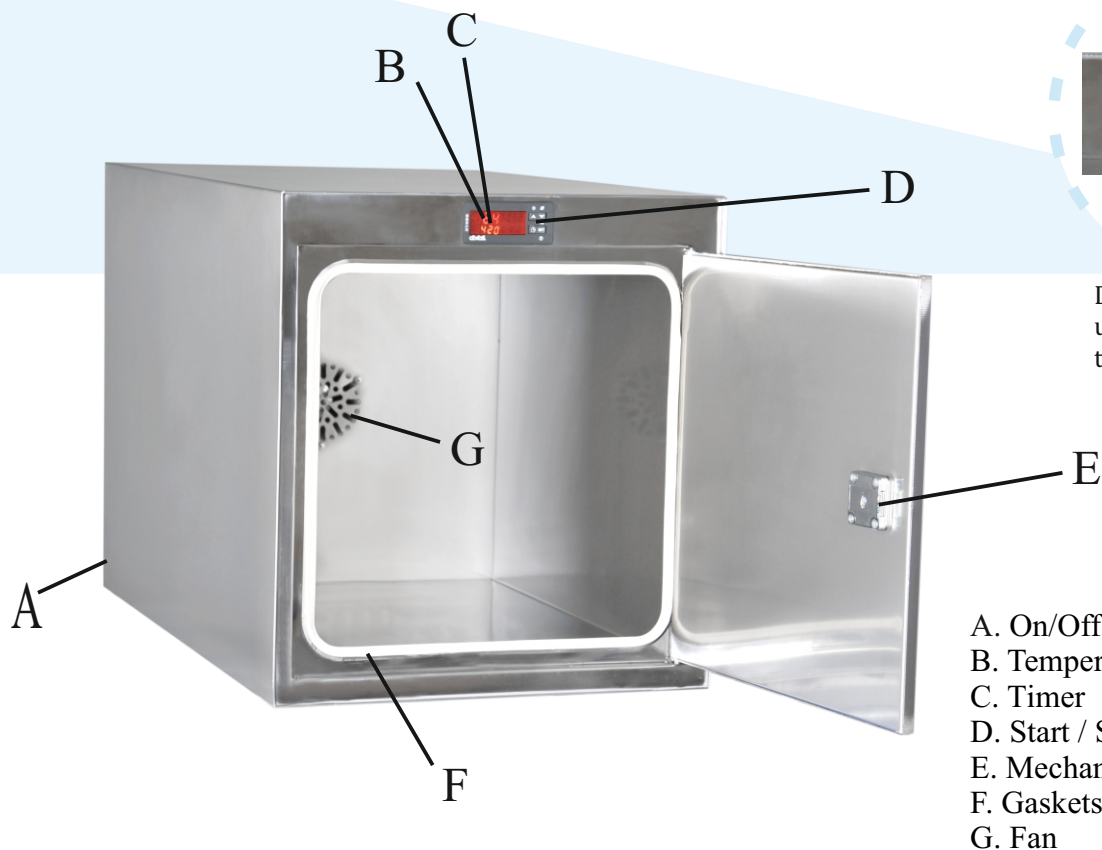
How does it work?

Simply put items to be sterilized into the Liner bag along with the Gas Ampoule and Humidity Chip than seal the liner bag with any sealing machine or tie-wrap. Then when placing the Liner Bag in the sterilizer, activate the EO gas cartridge and the sterilization process will begin.

Liner bags allows EO gas circulation due its permable stucture. According to EO Gas Sterilizer volume, liner bag dimensions will change.

Humidity chips provide essential moisture inside the bag.





Dixell controller allows user to set up temperature, time, stop and start the cycle.

- A. On/Off Switch / EMERGENCY STOP
- B. Temperature Indicator
- C. Timer
- D. Start / Stop Button
- E. Mechanical Door Lock
- F. Gaskets
- G. Fan

AXIS Sterilizers do not require any pressurized air, water, or drainage. All that is required is a 220V earthed electricity supply and an opening in a wall/window through which the outlet pipe of 6 cm diameter can be connected to the atmosphere.

Axis AX-1800 EO Gas Alarm



Instant tracking on the screen.
EO concentration measurement in the range of 0-99 ppm.
Microprocessor controlled.
Visual and auditory alarm (> 85 dB).
Adjustable alarm level.
Automatic calibration.
External alarm output.
Can be mounted on the wall.
High reliability.
220V 50Hz.
2-year warranty including sensor.
Sensor life of up to five years

Kordon Tip Recommends

The advantages of EO Sterilization;

- The widest range of material and product compatibility
- Ability to sterilize long, narrow, and multi-channel lumens.
- All sides and surfaces will be sterilized
- Compatible with all common packaging materials.
- Does not damage delicate instruments like harsh chemical sterilants.

You Tube : Axis EO Sterilizers



AXIS ETHYLENE OXIDE AMPOULE BASED CARTRIDGES



Dosimeters integrators along time, temperature and EO concentration, plus check presence of adequate water vapor levels (relative humidity) which is last parameter of ETO sterilization. If color change yellow to blue must extend at least to the pointer, thus indicating that a dose of 750 mg/liter-hours has been received.

% 80 less gas consumption than the competitors

With Axis's match load to cartridge method you never have to worry about tanks of EtO. Axis Products offers cutting-edge technologies and expertise in sterilization with the only system that offers multi load capability. The new diffusion chamber provides extra protection to the operator in case of accidental activation. Its robust design and polyurethane body make the EO Gas cartridge one of the most reliable tool for releasing the ethylene oxide gas. Operator safety is insured by the double protection of the trigger via a plastic lock and a safety seal.

Using sterilizing gas ampoules is a very simple method that can be performed anywhere, specially under emergency conditions. No electric power, natural gas, etc. connections are necessary. This method allows sterilizing any sort of materials, including those ones that cannot be exposed to steam environment in either autoclave or heat. Mainly, this gas penetrates into and spreads through different materials thus achieving proper sterilization.

Cartridges;

Code	Active Ingredient	Other Ingredients	Shield	Net Contents
AX 11	%96	%4	Polyurethane	11g to 15g
AX 20	%97	%3	Polyurethane	15g to 20g
AX 22	%97	%3	Polyurethane	20g to 22g

Cartridge Packs;

Code	Cartridge	Liner Bag	Humidity Chip	Dosimeter
AR 11	AX 11	22" x 36"	Included	Included
AR 20	AX 20	22" x 36"	Included	Included
AR 22	AX 22	22" x 36"	Included	Included



C E R T I F I C A T E

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Kordon Tıp Sağlık Araç Gereçleri Müh. Prj. İth. San. Tic. Ltd. Şti.

Company Address : 10006/1 Sokak No:43 A.O.S.B. Çiğli, İZMİR / TURKEY

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

Product : Ethylene Oxide Sterilizer - Class IIb
Ethylene Oxide Sterilization Cartridges - Class IIb
Ethylene Oxide Sterilization Cartridge Packs - Class IIb

GMDN : 13740, 44834

Product Types are attached.

Certificate Number : M.2017.106.7586
Report Number : MD.3232.YB
Initial Assessment Date : 14.10.2016
Registration Date : 17.01.2017
Recertification Assessment Date : 26.11.2019
Reissue Date / No : 25.03.2020/01
Revision Date /No : -
Expiry Date : 27.05.2024


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

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design-examination certificate is required for placing the Class II devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr



This document containing 1 (one) pages is the Annex of the Certificate with the number M.2017.106.7586 and with the registration date of 17.01.2017 and with the re-issue date 25.03.2020 issued for "Kordon Tıp Sağlık Araç Gereçleri Müh. Prj. İth. San. Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Ethylene Oxide Sterilizer
Model
AX 60
AX 135
AX 160
AX 200
AX 225
AX 400
AX 450
AX 1000
AX 2000
AX 4000
AX 6000
AX 9000

Ethylene Oxide Sterilization Cartridges
Model
AX 5
AX 6
AX 7
AX 8
AX 9
AX 10
AX 11
AX 12
AX 13
AX 14
AX 15
AX 16
AX 17
AX 18
AX 19
AX 20
AX 21
AX 22
AX 23
AX 24
AX 25
AX 26
AX 27
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AQ 21
AQ 22
AQ 23
AQ 24
AQ 25
AQ 26
AQ 27
AQ 28
AQ 29
AQ 30
AL 7
AL 25
AL 67
AL 100
AX 67
AX 100
AX 127
AX 134
AQ 70
AQ 120
AQ 130
AQ 170
AQ 200
AQ 230

Ethylene Oxide Sterilization Cartridge Packs
Model
AR 5
AR 6
AR 7
AR 8
AR 9
AR 10
AR 11
AR 12
AR 13
AR 14
AR 15
AR 16
AR 17
AR 18
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ARQ 5
ARQ 6
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ARQ 19
ARQ 20
ARQ 21
ARQ 22
ARQ 23
ARQ 24
ARQ 25
ARQ 26
ARQ 27
ARQ 28
ARQ 29
ARQ 30



Certificate of Registration

This is to certify that
Quality Management System
of

**KORDON TIP SAĞLIK ARAÇ GEREÇLERİ
MÜHENDİSLİK PROJE İTHALAT LTD. ŞTİ.**

10006/1 NO:43 A.O.S.B. ÇİĞLİ - İZMİR / TÜRKİYE
Branch: 354. SOK NO:4 2. SANAYİ SİTESİ BORNOVA - İZMİR / TURKEY

complies with requirements of

ISO 9001:2015

This certificate is valid concerning all activities related to;

MANUFACTURING, DESIGN AND SALES OF ETHYLENE OXIDE STERILIZERS AND ETHYLENE OXIDE CARTRIDGES. PRODUCT REALIZATION AND SALES OF BIOLOGICAL INDICATORS, STERILIZATION REELS, CHEMICAL INDICATORS, AUTOCLAVE TAPES, STERILIZATION DOCUMENTATION LABEL CHEMICAL INDICATORS, ETHYLENE OXIDE CARTRIDGE STORAGE CONTAINERS, WASHER INDICATORS, AUTOMATIC CARTRIDGE ACTIVATORS AND CONTAINERS, ETHYLENE OXIDE DETECTORS, AUTOCLAVEABLE BIOHAZARD BAGS, PATIENT TRANSFER SYSTEM, BOWIE & DICK TEST PACKS, WRAP PAPERS, BIOLOGICAL INDICATOR INCUBATORS, CHEMICAL VAPOR INDICATOR CLASS V FEED, EO INDICATOR CHEMICAL CLASS V FEED, RESIDUAL PROTEIN TEST, ULTRASONIC WASHING INDICATOR, STERILIZATION ENVELOPES, SELF ADHESIVE CHEMICAL THEY INDICATOR, HELIX CARGO CONTROL INDICATOR, LABEL GUN, WASH INDICATOR APPARATUS, PCD APPARATUS, STERILIZATION VALIDATION AND CALIBRATION SERVICE, STERILIZATION REEL SEALING, CUTTING AND PRINTING MACHINE, NEUTRALIZATORS, HEADER BAGS, WORK STATIONS, HANGER - CUTTER APPARATUS

ISO 01 794 488
Certificate No.

Jan. 10, 2022
Date of this Certificate

Jan. 2, 2023
Certification Expiry Date

Dec. 7, 2021
Date of Audit

Jan. 3, 2020
Date of Registration


Managing Director / Director



Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

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Certificate of Registration

This is to certify that

**Quality Management System
for Medical Devices**

of

**KORDON TIP SAĞLIK ARAÇ GEREÇLERİ
MÜHENDİSLİK PROJE İTHALAT LTD. ŞTİ.**

10006/1 NO:43 A.O.S.B. ÇIĞLI - İZMİR / TÜRKİYE

Branch: 354. SOK NO:4 2. SANAYİ SİTESİ BORNOVA - İZMİR / TURKEY

complies with requirements of

ISO 13485:2016

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ISO 02 795 488

Certificate No.

Jan. 10, 2022

Date of this Certificate

Jan. 2, 2023

Certification Expiry Date

Dec. 8, 2021

Date of Audit

Jan. 3, 2020

Date of Registration



Managing Director / Director



Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
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Saver One[®]

Complete AEDs range to save lives.



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

www.amiitalia.com

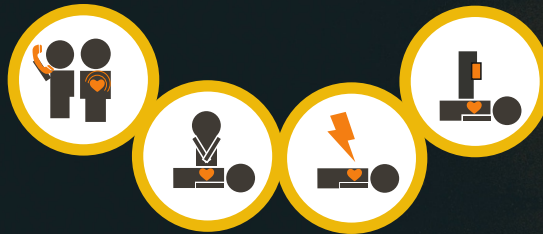
THE IMPORTANCE OF AEDs TO BEAT/WIN SCA

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.

CHAIN OF SURVIVAL



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.

SaverOne®





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

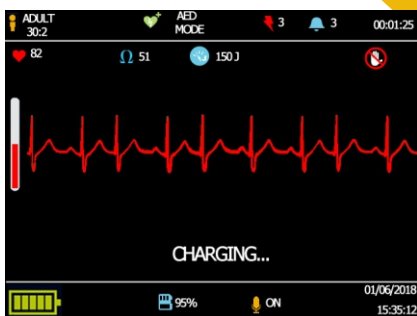
Operation:	AED Semi-Automatic ECG Monitoring capability
Energies:	Standard max 200J or Power max 360J
Waveform:	Adaptive BTE (biphasic truncated exponential) conforming to patient chest's impedance
AED Protocols:	Various adult shock protocols available on request
Factory default:	Adult Standard escalating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



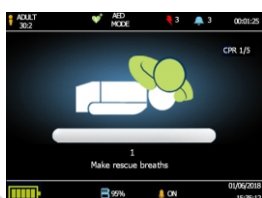
ABOUT DEVICE:

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



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 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

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 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

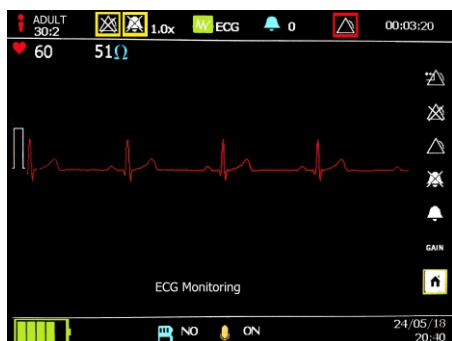
Code SVP-B0006:	Standard Version with maximum energy at 200J
Code SVP-B0007:	Power Version with maximum energy at 360J

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

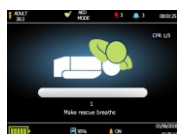
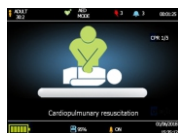


ABOUT DEVICE:

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

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ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

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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

CERTIFICATO N.
CERTIFICATE N. **9124.AMI2**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT 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 15/A - 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	2022-02-03	2025-03-19

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

CISQ is a member of



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IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.*



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

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

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT 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 15/A - 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	2022-02-03	2025-03-19

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

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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



Organismo di Certificazione Federato CISQ
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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 15/A - 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: 2022 - 02 - 03

Expires on: 2025 - 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. Mario Romersi
President of CISQ

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
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* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com