ORDIN DE PLATA NR.: 98 TIP.DOC. 1

DATA EMITERII:26 iulie 2022

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

PLATITOR: (R) S.C. "OXIVIT-MED" S.R.L.
CONTUL DE PLATI/CODUL IBAN MD44ML000000002251729503
CODUL FISCAL :1007600044280 /

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

BENEFICIAR (R) Centrul pentru Achizi?ii Publice Centralizate 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 garantia pentru oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-16288 66063582 din 18.09.2021

TIPUL TRANSFERULUI NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:101:
DATA PRIMIRII:26/07/2022
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Kojevnikov Dmitrii
MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbgxCzAJBgNVBAYTAk1EMRow:
YDVQQIExFSZXB1YmxpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxFzAV
(semnatura electronica)

CONTABIL-SEF:Web Kojevnikov Dmitrii
MIIGfAYJKoZIhvcNAQcCoIIGbTCCBmkCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBIUwggSBMIIDaaADAgECAhNHAACEjCA/4xcrKCbfAAAAAISMMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIwMDMxNjA4NDUwM1oXDTIzMDMxNjA4NTUwM1owgbgxCzAJBgNVBAYTAk1EMRow:
YDVQQIExFSZXB1YmxpY2EgTW9sZG92YTERMA8GA1UEBxMIQ2hpc2luYXUxFzAV
L.S. (semnatura electronica)

CONDUCATOR: (semnatura manuala)

CONTABIL-SEF: (semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Kojevnikov Dmitrii
Date: 2022.07.26 12:50:26 EEST
Reason: MoldSign Signature
Location: Moldova

MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **8871** din **05.05.2021**

Denumirea completă: **Societatea Comercială «OXIVIT-MED» S.R.L.**
Denumirea prescurtată: **S.C. «OXIVIT-MED» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1007600044280.**
Data înregistrării de stat: **30.07.2007.**
Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
2 Comerţul cu ridicata al parfumurilor şi produselor cosmetice;
3 Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă;
4 Intermedieri pentru vînzarea unui asortiment larg de mărfuri;
5 Alte tipuri de comerţ cu amănuntul în magazine nespecializate;
6 Alte tipuri de comerţ cu ridicata;
7 Închirierea altor maşini şi echipamente.
Capitalul social: **5400** lei.
Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,
Asociaţi:
1. KOJEVNIKOV DMITRII , IDNP 0972305012362
cota 5400.00 lei, ce constituie 100 %.

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: 05.05.2021.

Specialist coordonator
tel. 022-207-840
Lazari Aliona

Date cu caracter personal. **Operator: I.P. "Agenţia Servicii Publice" IO 0000059**

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

Anexa nr.7.2 la Instrucţiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existenţa restanţelor faţă de bugetul public naţional

Nr. / № A2213735 **din** / от 21.07.2022

1. Destinaţia / Назначение

AGENȚIA ACHIZIȚII PUBLICE

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
S.C. OXIVIT-MED S.R.L.	1007600044280
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localităţii** / Код - Наименование населенного пункта
Decebal bd. nr.82 of.90	0110-SEC.BOTANICA

3. Atestarea lipsei sau existenţei restanţelor conform datelor Sistemului Informaţional 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 pînă la / Действителен до 05.08.2022

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

MINISTERUL FINANȚELOR AL REPUBLICII MOLDOVA • SERVICIUL FISCAL DE STAT • IDNO 1006601001182

Șef interimar al DDF Botanica — Maiana VOLOH

Funcţia/Должность — Semnătura/Подпись — Numele şi prenumele/Фамилия и имя

L.Ş.M.Ţ.

Executor: Galina Ginga

Numele şi prenumele/Фамилия и имя

Este extras din Sistemul Informaţional al SFS SIA „Contul curent al contribuabilului"// 21.07.2022 ora 15:45:58 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)

MINISTERUL MEDIULUI
AL REPUBLICII MOLDOVA

MINISTRY ENVIRONMENT
OF THE REPUBLIC OF MOLDOVA

AGENŢIA DE MEDIU

ENVIRONMENTAL AGENCY

MD-2005 mun.Chişinău, str. Albişoara, 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 şi electronice)

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

MD2022-1-EEE-002

pentru OXIVIT-MED SRL, IDNO: 1007600044280, cu adresa juridică: mun. Chișinău, str. Decebal 82, ap.(of.) 90.

Numărul de înregistrare este valabil începînd cu data de 19.01.2022 pînă la data de 19.01.2025.

Director adjunct interimar
Gavril GÎLCA

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

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2021 - 31.12.2021

Entitatea: S.C. OXIVIT-MED S.R.L.
Cod CUIÎO: 40424951
Cod IDNO: 1007600044280

Sediul:
MD:
Raionul(municipiul): 103, DDF BOTANICA
Cod CUATM: 0110, SEC.BOTANICA
Strada: Decebal bd. nr.82 of.90

Activitatea principală: G4774, Comert cu amanuntul al articolelor medicale si ortopedice, in magazine specializate
Forma de proprietate: 15, Proprietatea privată
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: +37322808002
WEB:
E-mail: oxivit.medical@gmail.com
Numele și coordonatele al contabilului-șef: Dl (dna) Kojevnikov Dmitrii Tel. 069200308

Numărul mediu al salariaților în perioada de gestiune: 5 **persoane.**

Persoanele responsabile de semnarea situațiilor financiare* Kojevnikov Dmitrii

Unitatea de măsură: leu

BILANȚUL

Anexa 1

la 31.12.2021

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	1137	487
	din care: 2.1. concesiuni, licențe și mărci	021	1137	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	1137	487
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	9980	45953
	din care: 3.1. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	9235	45953
	3.4. mijloace de transport	084		

A.	3.5. inventar și mobilier	085		
	3.6. alte mijloace fixe	086	745	
	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	9980	45953
	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	11117	46440
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	617	752
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	6895348	8612039
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	6895965	8612791
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	17423930	9151659
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	1593996	685035
	4. Creanțele ale personalului	330	1452	
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350	6076	4940
	7. Alte active circulante	360	3786977	5022901
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	22812431	14864535
	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	11586107	10982450
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	41294503	34459776
	TOTAL ACTIVE (rd.230 + rd.420)	430	41305620	34506216
	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	-178779
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	24939574	17439574
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	11125729
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	24939574	28386524
	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	24944974	28391924
D.	**DATORII PE TERMEN LUNG**			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640	76630	
	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	76630	
	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	76630	
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	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	15784405	4868225
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	349631	938523
	6. Datorii față de personal	760	116957	107832
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780		199712
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	33023	
	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	16284016	6114292
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	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	41305620	34506216

SITUAŢIA DE PROFIT ŞI PIERDERE

de la 01.01.2021 pînă la 31.12.2021

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	61054881	63146813
din care: venituri din vînzarea produselor și mărfurilor	011	61054881	63146813
venituri din prestarea serviciilor și executarea lucrărilor	012		
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanţare	015		
alte venituri din vînzări	016		
Costul vînzărilor, total	020	50207602	48882405
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	50207602	48882405
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanţare	025		
alte costuri aferente vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	10847279	14264408
Alte venituri din activitatea operațională	040	1967064	9915
Cheltuieli de distribuire	050	68333	60149
Cheltuieli administrative	060	995848	968411
Alte cheltuieli din activitatea operațională	070	34858	239797
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	11715304	13005966

Venituri financiare, total	090	1752762	1026285
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093		1440
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	1752762	1024845
Cheltuieli financiare, total	100	1580853	1210147
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	1580853	1210147
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	171909	-183862
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		174839
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		-174839
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	171909	-358701
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	11887213	12647265
Cheltuieli privind impozitul pe venit	170	1431875	1521536
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	10455338	11125729

SITUAŢIA 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				

SITUAŢIA 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)

Versiune de imprimare
Salvare

Recipisa

Respondent
Codul fiscal: 1007600044280, denumire: S.C. OXIVIT-MED S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2021
Data prezentarii: 30.05.2022
Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 30.05.2022 16:42:42

Versiune de imprimare
Salvare

Recipisa 2

Respondent
Codul fiscal: 1007600044280, denumire: S.C. OXIVIT-MED S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2021
Data prezentarii: 30.05.2022
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 30.05.2022 22:47:31

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) – Italy
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

CERTIFICATO

Reg. Numero	10164 - A	Valido da	2021-10-14
Primo rilascio	2012-10-15	Ultima modifica	2021-10-14
Scadenza	2024-10-14	Settore IAF	29 a

Certificato del Sistema di Gestione per la Qualità

ISO 9001:2015

Si dichiara che il sistema di gestione per la Qualità dell'Organizzazione:

GIMA S.p.A.

è conforme alla norma UNI EN ISO 9001:2015 per i seguenti prodotti/servizi:

Commercializzazione, confezionamento ed assistenza di: dispositivi medici (DM), diagnostici in vitro (IVD), dispositivi di protezione individuale (DPI), biocidi (PMC), dispositivi per veterinaria, accessori, arredi e supporti ad uso medico

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali di Kiwa Cermet Italia.

Il presente certificato è costituito da 1 pagina.

GIMA S.p.A.
Sede Legale
- Via Grossi, 2 20121 Milano - Italia

Sedi Oggetto di Certificazione
- Via Marconi, 1 20060 Gessate (MI) - Italia

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.kiwa.it

SGQ N° 007A

CERTIFICATE

Reg. Number	10164 - A	Valid From	2021-10-14
First issue date	2012-10-15	Last change date	2021-10-14
Valid Until	2024-10-14	IAF Sector	29 a

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.kiwa.it

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano - Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) - Italia

CERTIFICATO

Reg. Numero	10164 - M	Valido da:	2021-10-14
Primo rilascio	2012-10-15	Ultima modifica	2021-10-14
Scadenza	2024-10-14		

Certificato del Sistema di Gestione per la Qualità

ISO 13485:2016

Si dichiara che il Sistema di Gestione per la Qualità dell'Organizzazione:

GIMA S.p.A.

è conforme alla norma UNI CEI EN ISO 13485:2016 per i seguenti prodotti/servizi:

Gestione della progettazione e della produzione, confezionamento e assistenza di: Dispositivi medici generali non attivi e non impiantabili (eccetto: iniezione, infusione, trasfusione, dialisi; disinfezione, pulizia, risciacquo; IVF e ART; ingestione), Dispositivi per la cura delle ferite, Dispositivi dentali non attivi e accessori (eccetto impianti dentali), Dispositivi medici generali attivi (eccetto: circolazione extracorporea, infusione, emaferesi; stimolazione o inibizione; riabilitazione e protesi attive; IVF e ART; software; sistemi di gas medicali e relative parti); Dispositivi di monitoraggio; Dispositivi per immagini e termoterapia (eccetto: radiazioni ionizzanti, litotripsia); Diagnostici in vitro (IVD).
Commercializzazione e assistenza di: Dispositivi medici generali non attivi e non impiantabili (eccetto: IVF e ART; ingestione), Dispositivi per la cura delle ferite, Dispositivi dentali non attivi e accessori (eccetto impianti dentali), Dispositivi medici generali attivi (eccetto: IVF e ART), Dispositivi per acquisizione immagini (eccetto radiazioni ionizzanti), Dispositivi di monitoraggio, Dispositivi per radioterapia e termoterapia (eccetto: radiazioni ionizzanti, litotripsia); Diagnostici in vitro (IVD).

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali di Kiwa Cermet Italia.

Riferirsi al manuale qualità per i dettagli delle esclusioni ai requisiti della norma UNI CEI EN ISO 13485:2016.

Il presente certificato è costituito da 1 pagina.

GIMA S.p.A.
Sede Legale
- Via Grossi, 2 20121 Milano Italia

Sedi Oggetto di Certificazione
- Via Marconi, 1 20060 Gessate (MI) Italia

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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E-mail: info@kiwacermet.it
www.kiwacermet.it

SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C

CERTIFICATE

Reg. Number	10164 - M	Valid From	2021-10-14
First issue date	2012-10-15	Last change date	2021-10-14
Valid until	2024-10-14		

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:

Management of design and production, packaging and service of:
General non-active, non-implantable medical devices (except: injection, infusion, transfusion and dialysis; disinfecting, cleaning, rinsing; IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except: extra-corporal circulation, infusion and haemopheresis; stimulation or inhibition, rehabilitation devices and active prostheses; IVF, ART; software; medical gas supply systems and parts thereof), Monitoring devices, Devices for imaging and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices (IVD).
Trade and service of: General non-active, non-implantable medical devices (except: IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except IVF, ART), Devices for imaging (except ionizing radiation), Monitoring devices, Devices for radiation therapy and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices(IVD)

Chief Operating Officer
Giampiero Belcredi

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

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
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www.kiwa.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

CLINIC PLUS SUCTION 2x2 l jar 230V

Code:	**28194**
Category:	**Hospital suction pumps - aspirators**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**II A**
NSIS:	**590729**
CND:	**Z120105**
EAN13:	**8023279281941**

Description:

CLINIC PLUS Basic
• Autoclavable Jars: 2x2 l
• Footswitch: NO
• Flow direction diverter (Allows to direct suctioned liquids to any of the 2 jars): NO

Designed for professional aspiration of bodily fluids, tissues or bones of patients during or after surgery.
Oiless and maintenance free piston type pumps provide high performances. Excellent suction capacities and max vacuum built up within a few seconds.
Available with vacuum gauge and autoclavable jars made in makrolon with 200 ml (2 l jar) or 500 ml (4 or 5 l jars) graduation and 2-3 litres Flovac jars with disposable liners.

Wide range of versions with different features
- 60 l/m (Clinic Plus) or 90 l/m (Hospi Plus) flow rate
- 2, 4 or 5 l jars
- MPR system for versatility
- footswitch and flow direction diverter

High standards of safety in overflow protection system
Double security valve integrated in the jar and hydrophobic filter (all models), safety trap bottle (only MPR models).

MPR (Multi Purpose Rail) models
This system enhances the versatility for easy and quick exchange of different accessories, with no need for tools.

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

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

Size: 460 x 850 x 420 mm
Weight: 20 kg
Made in Italy.

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

	Maximum suction: - 0,90 bar (675 mmHg) **Operating cycle: continuous** **Flow: 60 l/min** **Power: 230 VA** **Noise level: 51.7 dBA** **Norms: CEI 62-5 (IEC 601-1); 93/42 EEC**
Standard accessories:	**121°C autoclavable jar with overflow valve system: 2x2 l** **Rings to accommodate 5 l jars: NO** **Safety Trap Bottle (220 ml): NO** **Antibacterial & Hydrophobic Filter (single-patient): 1** **Autoclavable silicone tubes ø 8x14 mm length 150 cm: 1** **Conical Connector ø 10-11-12mm: 1** **Air suction inlet: 1** **Footswitch with intermittent or continuous operation: NO** **Change-Over System from jar to jar by soft-touch keys: NO** **Power Cord with Schuko plug: 1** **Multilingual manual: GB, FR, IT, ES ,DE, GR, PL, RO**

SILICONE TUBE 8x14 mm - 3 mm thick

Code:	**25482**
Category:	**Silicone tubing**
Unit of sale:	**1 roll 30 m**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**2207981**
CND:	**V9099**
EAN13:	**8023279254822**

Description:

SILICONE TUBES for external medical use - silicone 100%

- Suitable for autoclaving (135°C - 2.2-2.5 bar) and Gamma Sterilization.
- Resistant to hot air up to 200°C.
- Infra-red vulcanization.
- Hours treatment at 200°C temperature in special oven.
- Anti-adherent, avoid incrustation and coagulation.
- Medical Grade - Transparent - Odourless

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

Internal Ø x external Ø 8 x 14 mm
Thinkness: 3 mm
Minimum order: roll of 30 m

MADE TO ORDER SILICONE TUBES
We can manufacture any size (minimum order 500 m - delivery 30 days)

Technical Specifications:

• Raw material: HTV-R-401/60 E - WACKER (D)
• Colour: translucent
• Hardness: 60° ±5% Shore - DIN 53505
• Density: 1.17 g/ccm - DIN 53479A
• Tensility: 10.8 N/mm2 - DIN 53504 S1
• Stretch: 490/530% - DIN 53504S1
• Tear resistance: 34-35 N/mm - ASTM D 624 B
• Reverse pull elasticity: 51% - DIN 53512
• Compression set: (22h/175°C): 30-15% - DIN 53517

SPARE FILTER for MaxiAspeed

Code:	**28297**
Category:	**Filtres**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**II A**
NSIS:	**2077807**
CND:	**R040101**
EAN13:	**8023279282979**
Description:	**Hydrophobic antibacterial filter**

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, 92618
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Implants and Instruments for Interventional Minimal Invasive Therapy according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	281863 MR2
Certificate unique ID	170766328
Effective date	2020-03-11
Expiry date	2024-05-26
Frankfurt am Main	2020-03-11

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170766328
Effective date: 2020-03-11

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, 92618
United States of America

Device family	Device	Class
Detachable Embolization Coils	Axium™ Helix	III
	Axium™ 3D	III
	Axium™ Nylon Helix	III
	Axium™ PGLA Helix	III
	Axium™ PGLA 3D	III
	Axium™ Prime Bare Platinum Helix	III
	Axium™ Prime Bare Platinum 3D	III
	Axium™ Prime Frame Complex	III
	Concerto™ Bare Platinum Helix	IIb
	Concerto™ Bare Platinum 3D	IIb
	Concerto™ PGLA Fiber Helix	III
	Concerto™ PGLA Fiber 3D	III
	Concerto™ Nylon Fiber Helix	IIb
Neurovascular Remodeling Devices	Solitaire™ AB Neurovascular Remodeling Device	III
	Pipeline™ Flex Embolization Device (PFED)	III
	Pipeline™ Flex Embolization Device with Shield Technology™ (SHIELD)	III
	Pipeline™ Vantage Embolization Device with Shield Technology™ (PED3)	III
Detachment Devices	Solitaire™ NDS-2x Detachment System	IIa
	Cable Set Sterile (NCS),	Is
	Solitaire Cable Set (CSS),	Is
	Instant Detacher (I.D.)	Is
Revascularization Devices	Solitaire™ 2 Revascularization Device	III
	Solitaire™ Platinum Revascularization Device	III
	Solitaire™ X Revascularization Device	III
Liquid Embolic Systems	Onyx™ Liquid Embolic System (LES)	III
	Onyx™ Aneurysm System (Onyx HD-500)	
Infusion Catheters	Cragg McNamara™ Catheter	IIb
	MicroMewi™ Infusion Catheter	IIb
Infusion Wires	ProStream™ Infusion Wire	IIb
Balloon Occlusion Catheters	HyperGlide™ Occlusion Balloon System	III
	HyperForm™ Occlusion Balloon System	III

Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170766328
Effective date: 2020-03-11

Micro Therapeutics, Inc.
DBA ev3 Neurovascular

9775 Toledo Way
Irvine, 92618
United States of America

Device family	Device	Class
Syringe Adapters, Syringes and Introducer Sheaths	Echelon™ Syringe Adapter	Is
	Cadence™ Precision Injector Accessory	Is
	Onyx™ Syringe Catheter Interface Adapter	Is
	1mL Syringe	Is
Guide Wires	Mirage™ Hydrophilic Guidewire	III
	X-Pedion™ Hydrophilic Guidewire	III
	Avigo™ Hydrophilic Guidewire	III
Micro Catheters	Marksman™ Catheter	III
	Nautica™ Micro Catheter	III
	Echelon™ Micro Catheter	III
	Rebar™ Micro Catheter	III
	Orion™ Micro Catheter	III
	Phenom™ Catheter	III
Flow Directed Catheters	Marathon™ Flow Directed Micro Catheter	III
	Apollo™ Onyx™ Delivery Micro Catheter	III
Guide Catheter	Navien™ A+ Intracranial Catheter	III
	React™ 68 Catheter	III
	React™ 71 Catheter	III
Surgical irrigation/aspiration system	Riptide™ Aspiraton Pump	IIa
	Riptide™ Large Bore Aspiration Tubing	Is

CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

ISO 9001:2015
EN ISO 13485:2016

Scope:
Sales, order management, warehousing and distribution of medical devices.
Including regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2024
Certificate effective date: 1 July 2021
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

MGMT. SYS. RvA C 589

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:

	Different scope
Medtronic Trading NL B.V. Larixplein 4 5616 VB Eindhoven The Netherlands	Sales, order management and distribution of medical devices. Including customer education
Medtronic Italia S.p.A. Via Varesina 162 20156 Milano Italy	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Danmark A/S. Arne Jacobsens Alle 17 2300 Kopenhagen Denmark	Sales, order management and distribution of medical devices. Including customer education
Medtronic Finland Oy Lentajantie 3 01530 Vantaa Finland	Sales, order management and distribution of medical devices. Including customer education.
Medtronic AB P.O. Box 1034 164 21 Kista Sweden	Sales, order management and distribution of medical devices. Including customer education
Medtronic Norge AS Martin Linges vei 25 1364 Fornebu Norway	Sales, order management and distribution of medical devices. Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd. Waterfall Distribution Campus CNR K101 and Bridal Veil Road Waterfall Midrand 1685 Gauteng South Africa	Sales, order management, warehousing and distribution of medical devices. Including customer education and spine loaner operations.
Medtronic Medikal Teknoloji Ticaret Ltd Sti Saray Mah. Esnaf Sk. Akkom Ofis Park Laodik Plaza Sitesi B Blok Apt: 2/8 34764 Umraniye - Istanbul Turkey	Sales, order management and distribution of medical devices. Including customer education
Medtronic Ibérica S.A. Calle de Maria de Portugal, 11 28050 Madrid Spain	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Ibérica S.A. WTC Almeda Park Placa de la Pau, s/n. Edificio 7, 3 piso Cornella de Llobregat 08940 Barcelona Spain	Sales, order management and distribution of medical devices.
Medtronic Portugal LDA- Rua Tomas da Fonseca Torre E, 11 piso 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices including customer education. Warehousing and distribution of medical devices, including spine loaner operations

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Medtronic EMEA Medtronic B.V.

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6422 PJ Heerlen

Medtronic Portugal, LDA- Avenida Gomes Pereira 61B Benfica 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices. Including customer education. Warehousing and distribution of medical devices, including spine loaner operations.
Medtronic GmbH Earl-Bakken-Platz 1 40670 Meerbusch Germany	Scope for EN ISO 13485:2016: Sales, order management and distribution of medical devices. Including customer education. ISO 9001:2015 excluded
Medtronic GmbH Mollsfeld 12 40670 Meerbusch Germany	Scope for EN ISO 13485:2016: Sales, order management and distribution of medical devices. Including customer education. ISO 9001:2015 excluded
Medtronic Osterreich GmbH Milennium Tower, 20th floor Handelskai 94-96 1200 Wien Austria	Sales, order management, warehousing and distribution of medical devices. Including customer education
Medtronic (Schweiz) AG Talstrasse 9 3053 Munchenbuchsee Switzerland	Sales, order management, warehousing and distribution of medical devices. Including customer education
Medtronic France SAS 9, boulevard Romain Rolland 75014 Paris France	Sales, order management and distribution of medical devices. Including customer education

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Medtronic Hellas S.A. Avenue Kifisias 24 Building B 151 25 Marousi Pref. Attica Greece	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Hellas S.A. Diabetes Shop Mesogeion Avenue 2-4 115 27 Athens Greece	Sales, order management and distribution of diabetes medical devices. Including customer education.
Medtronic Romania SRL Ploiesti 42-44, Building B, B2 Wing, 2nd floor, district 1 Baneasa Business & Technology Park 013696 Bucharest Romania	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Hungária Kft. Bocskai ut 134-146 Cepulet 3. emelet 1113 Budapest Hungary	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Serbia Ltd. Bulevar Zorana Djindjica, 64a 11070 Belgrade Serbia	Sales, order management and distribution of medical devices. Including customer education.

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Medtronic Poland Sp.z o.o Medtronic Customer Care Center of Experience Warsaw Polna 11 00-633 Warszawa Poland	Order management of medical devices.
Medtronic Trading Ltd. 10 Hamada Street 4673344 Herzlya Israel	Import, sales, order management and distribution of medical devices. Including customer education
Medtronic Czechia s.r.o. Prosek Point, Budova B, Prosecka 852/66 852 66 Praha Czech Republic	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Bulgaria EOOD 48 Sitnyakovo blvd., R-N OBORISHTE DISTR., floor 7 1505 Sofia Bulgaria	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Limited Building 9, Croxley ParkHatters Ln WD18 8WW Watford United Kingdom	Sales, order management and distribution of medical devices. Including customer education.

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Medtronic Ireland Limited Block 3090-3094Lake Drive, Citywest Business Campus D24 NW2F Dublin Ireland	Sales, order management and distribution of medical devices. Including customer education.
Medtronic B.V. Medtronic Service & Repair EMEA Jan Campertstraat 21-A 6416 SG Heerlen	Order management, warehousing and technical service of medical devices including field service EMEA.
Medtronic Slovakia s.r.o. CBC III, Karadzicova 12 821 08 Bratislava Slovak Republic	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Belgium Burgemeester E. Demunterlaan 5 1090 Brussel Belgium	Sales, Order Management and distribution of medical devices. Including customer education
Medtronic Croatia Folnegoviceva 1c 10000 Zagreb Croatia	Sales, order management and distribution of medical devices. Including customer education.
Medtronic Slovenia Ameriska Ulica 8 1000 Ljubljana Slovenia	Sales, order management and distribution of medical devices

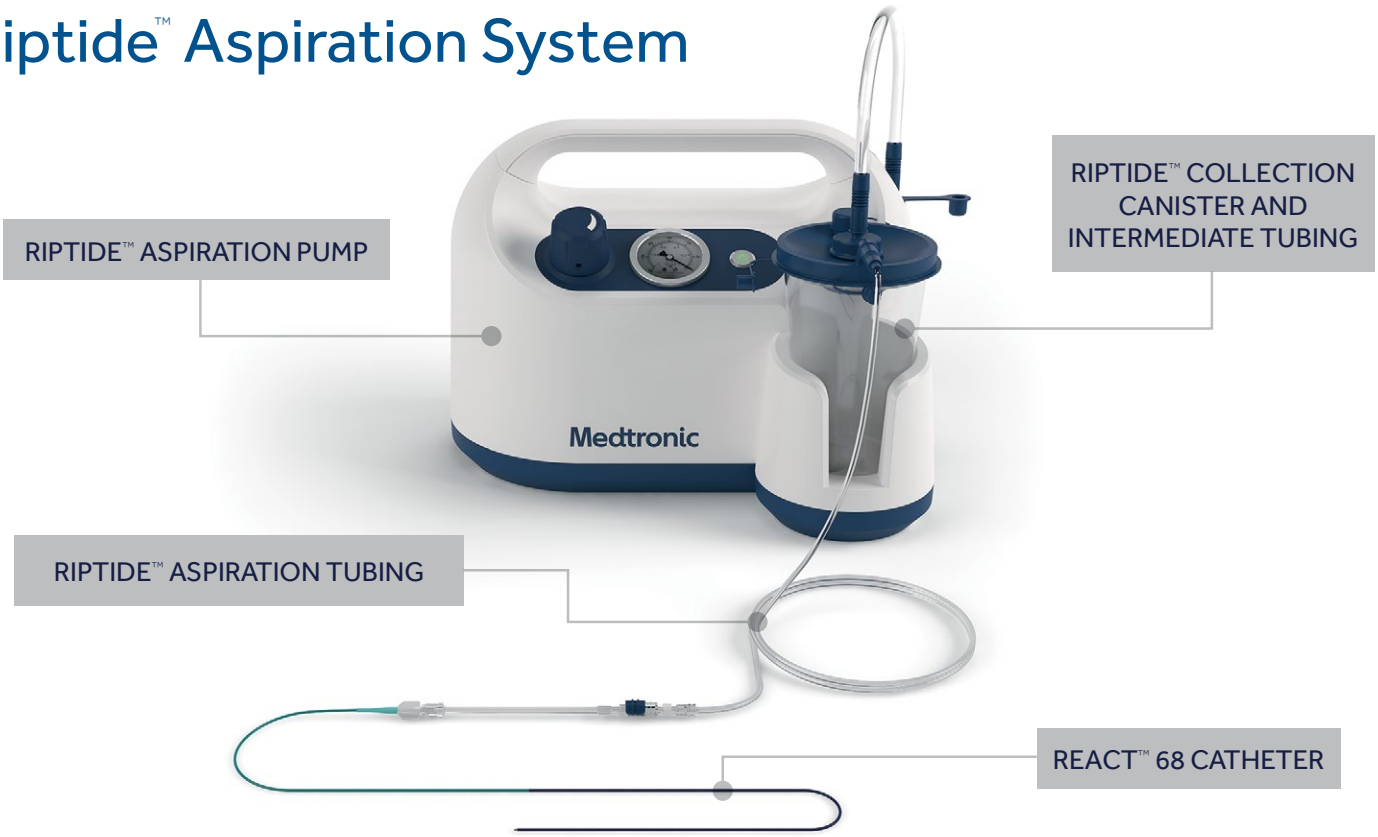
Addendum expiry date: 1 July 2024
Addendum effective date: 1 July 2021

EXPANDING YOUR OPTIONS. **EMPOWERING** YOUR EXPERTISE.

Riptide™
Aspiration System

Medtronic
Further, Together

Riptide™ Aspiration System



Individual Components

	Product Catalog Number	
Riptide™ Aspiration Pump	MAP-1000	

	Product Catalog Number	Volume	
Riptide™ Collection Canister & Intermediate Tubing[1]	MAC-1200	1200mL	

	Product Catalog Number	Inner Diameter	Tubing Length	Distal Length	
Riptide™ Aspiration Tubing[2]	AT-88-110	0.088"	112"	7"	

	Product Catalog Number	Working Length	Prox OD	Dist OD	Prox ID	Dist ID
React™ 68 Catheter[3]	REACT-68	132cm	0.083"	0.083"	0.068"	0.068"

Initial Order Bundle

	Product Catalog Number	Riptide™ Aspiration Pump	Riptide™ Collection Canister & Intermediate Tubing[1]	Riptide™ Aspiration Tubing	React™ 68 Catheter
Riptide™ Aspiration System 68 Bundle	RBUNDLE-68	1 Qty	3 Qty	3 Qty	3 Qty

Medtronic

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medtronic.com

1 PS16-009E Specification Conformance Matrix
2 DWGSAT-88-110 Rev. C Design Specification
3 DWGSREACT-68 Rev. C Design Specification

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
Indications, contraindications, warnings and instructions for use can be found on the product labeling supplied with each device.

The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

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Medtronic

Riptide™

Aspiration Pump

71048-001 Rev. A (10/2018)

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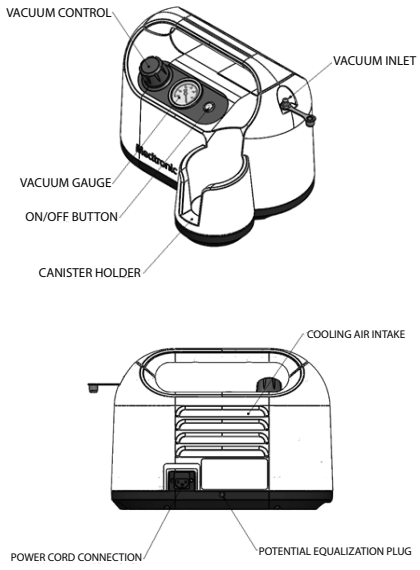

Figure 1: Riptide™ Aspiration Pump Features and Controls

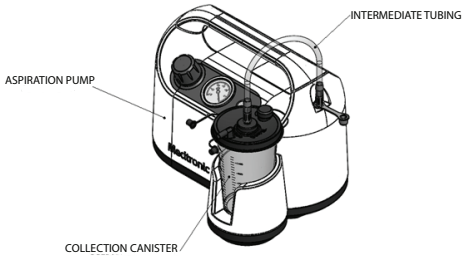

Figure 2: Riptide™ Aspiration Pump and Riptide™ Collection Canister with Intermediate Tubing

DESCRIPTION

- The Riptide™ Aspiration Pump is an externally powered electromechanical device capable of generating a vacuum designed for drawing fluids and small particles into the Riptide™ Collection Canister during neurovascular interventional procedures. It is intended for clinical and catheter lab use and is not intended for transport or field applications.
- The recommended operating range for the Riptide™ Aspiration Pump is between 20-25 inHg (68-85 kPa).
- The Riptide™ Aspiration Pump is intended for use as a component of the Riptide™ Aspiration System. The Riptide™ Aspiration System includes the Arc™ Catheter, React™ 68 Catheter, React™ 71 Catheter, Riptide™ Aspiration Tubing, Riptide™ Large Bore Aspiration Tubing, Riptide™ Aspiration Pump, and Riptide™ Collection Canister with Intermediate Tubing.
- Federal law (USA) restricts this device and other components of the Riptide™ Aspiration System to sale by or on the order of a physician.
- The Riptide™ Aspiration Pump package includes the following:
  - Riptide™ Aspiration Pump
  - Region specific power cord for connection to earthed receptacle. Select correct cord from included kit.
  - Riptide™ Aspiration System *Instructions for Use*
  - Riptide™ Aspiration Pump User's Manual
- Components used with the Riptide™ Aspiration System (packaged separately)
  - Arc™ Catheter, Applied Part
  - React™ 68 Catheter, Applied Part
  - React™ 71 Catheter, Applied Part
  - Riptide™ Aspiration Tubing, Applied Part
  - Riptide™ Large Bore Aspiration Tubing, Applied Part
  - Riptide™ Aspiration Pump
  - Riptide™ Collection Canister with Intermediate Tubing

INDICATIONS AND CONTRAINDICATIONS

- Refer to the Riptide™ Aspiration System *Instructions for Use* for indications and contraindications.

OPERATING DESCRIPTION

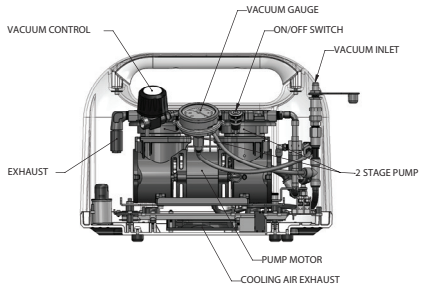

Figure 3: Riptide™ Aspiration Pump Internal Composition

The Riptide™ Aspiration Pump uses an industry proven oilless rocking piston type vacuum pump. A single, permanent split capacitor type electric motor powers a two stage pump arrangement that provides high vacuum and efficient flow through the Riptide™ Collection Canister. In a reciprocating motion, a flexible cup mounted on top of a wristless piston and connecting rod in each stage creates vacuum as the cup creates a vacuum as a result of the rocking motion. The vacuum is drawn in through the vacuum inlet and exhausted internally in the enclosure where it is mixed with cooling air and discharged through a vent located on the bottom.

WARNINGS

- The Riptide™ Aspiration System in contact with patients should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke. The Aspiration Tubing, Riptide™ Aspiration Pump, and Riptide™ Collection Canister with Intermediate Tubing are designed for setup by clinical support staff under the supervision of a trained physician.
- Do not use the Riptide™ Aspiration System with components other than the Arc™ Catheter, React™ 68 Catheter, React™ 71 Catheter, Riptide™ Aspiration Tubing, Riptide™ Large Bore Aspiration Tubing, Riptide™ Aspiration Pump, and Riptide™ Collection Canister with Intermediate Tubing.
- The Riptide™ Aspiration Pump is a Class I Medical Equipment. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

PRECAUTIONS

- The Riptide™ Aspiration Pump and the Riptide™ Collection Canister with Intermediate Tubing are supplied non-sterile and are intended for use outside of the sterile field only.
- Do not use the Riptide™ Aspiration Pump without the Riptide™ Collection Canister with Intermediate Tubing and connected to the vacuum inlet.
- The Riptide™ Aspiration Pump is intended for use only with the Riptide™ Collection Canister with Intermediate Tubing. The lid is equipped with integral overflow protection and a biological filter required for safe and correct operation in the Riptide™ Aspiration System. Using non-validated canisters, filters, or systems may result in improper patient connections, fluid overflow, biological contamination, and non-repairable damage of the Riptide™ Aspiration Pump.
- Do not allow aspirated fluids, overflow, or other liquids into the Riptide™ Aspiration Pump. This will cause non-repairable damage to the pump and create a biological contamination condition. Pumps so contaminated must be removed from service and disposed of in accordance with standard biological waste disposal procedures in effect.
- Aspiration Tubing and Riptide™ Collection Canister with Intermediate Tubing are single use only.
- The Riptide™ Aspiration Pump does not contain any user serviceable part inside. Do not attempt to open the enclosure.
- Do not use in presence of explosive atmospheres, flammable liquids or anesthetic mixtures, and nitrous oxide.
- Do not use in oxygen enriched environment.

SETUP

- Remove the Riptide™ Aspiration Pump from storage and/or its packaging (if present) and visually inspect for damage.
- Place the Riptide™ Aspiration Pump on a rigid, stable, flat, horizontal surface outside of the sterile field, within reach of the Aspiration Tubing and providing sufficient tubing slack to the patient table.
- The Riptide™ Aspiration Pump should be placed so that the tubing connections, controls and gauges are visible and accessible to the operator. The Riptide™ Aspiration Pump must never be positioned in a manner that makes it difficult to operate.
- Locate the Riptide™ Aspiration Pump such that a minimum of 6 inches (approximately 15cm) clearance exists in all directions to adjacent objects or other common cath lab equipment, powered or un-powered.
- Do not block the air vents located on the back and bottom of the enclosure. Do not place the pump on thick or plush absorbent table covering and do not cover the pump with poly or other sheeting during operation. Blocked air flow will result in pump overheating.
- Attach the correct end of the supplied power cord to the power connection on the back of the enclosure. Press in firmly and confirm its solid positioning.
- If required, attach the potential equalization connector to the potential equalization plug identified by a green/yellow disk located at the back of the pump.
- Confirm that the mains power available and the pump's nameplate ratings are compatible.
- The supplied power cords are the isolation mean and are detachable from the Riptide™ Aspiration Pump. The appliance connector is different from the mains connector. Push the cord's C13 receptacle into the appliance power inlet plug located at the back of the enclosure. At the other cord end, insert the power plug of the cord into the designated mains power receptacle – nominal 220-240VAC, 50/60HZ, 200VA minimum capacity. **NOTE:** The Riptide™ Aspiration Pump should not be positioned such that it is difficult to disconnect the supplied power cord.
- **NOTE:** Do not use electrical plug adapters instead of supplied power cord specific to region as use of adapter may result in damage to Riptide™ Aspiration Pump.
- The Riptide™ Aspiration Pump's power cable should not be bundled or held in proximity with other power cables that may carry very large surges and transients such as welders and large electric motors. In addition, separation from data cables and communications lines should follow EN50174-2:2008. In general, approximate separation from unshielded lines should be no less than 2 feet (approximately 61 cm), separation for shielded cables 2 inches (approximately 5 cm). Failure to follow these guidelines may result in electromagnetic interference due to radiated or re-radiated electrical noise.
- Check the basic operation of the Riptide™ Aspiration Pump by pressing the ON/OFF power switch on the front panel. The switch should light up green and the pump motor should start. The presence of vacuum can be confirmed by temporarily blocking the vacuum inlet with a finger and operating the pump's vacuum control valve while observing the vacuum gauge. Note that the tethered cap is not a vacuum seal and may not seal air tight without additional finger pressure on top. Turn the pump off by pressing the ON/OFF power switch before proceeding.
- Do not use the Riptide™ Aspiration Pump for aspiration without the Riptide™ Collection Canister with Intermediate Tubing connected to the vacuum inlet.
- Obtain a new Riptide™ Collection Canister with Intermediate Tubing and perform the setup in accordance with the Riptide™ Aspiration System *Instructions for Use* and the Riptide™ Collection Canister with Intermediate Tubing *Quick Reference Guide*.
- The Riptide™ Aspiration Pump is now ready to connect to Aspiration Tubing per the Riptide™ Aspiration System *Instructions for Use*.

OPERATION

- Refer to the Riptide™ Aspiration System *Instructions for Use* and the Riptide™ Collection Canister with Intermediate Tubing *Quick Reference Guide* to confirm complete setup for aspiration.
- With the Arc™ Catheter, React™ 68 Catheter, or React™ 71 Catheter, Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing, Riptide™ Aspiration Pump, and Riptide™ Collection Canister with Intermediate Tubing connected, the Riptide™ Aspiration Pump is ready to begin supplying vacuum to the connected components.
- Confirm that the flow control switch on the Aspiration Tubing is in the OFF position.
- The ON/OFF power switch on the control panel is a push button that requires moderate force inward to activate and de-activate. When depressed to the ON position, the button will lock in the recessed position, the green symbol will light, and the pump will begin to operate. When the button is depressed again and then released, the button will return to the original flush position, the green symbol will go dark, and pump will cease to run.
- At any time when the power switch is turned OFF after the Riptide™ Aspiration Pump is run, any vacuum present in the pump will be released. Then, the Riptide™ Collection Canister with Intermediate Tubing, and Aspiration Tubing proximal to the flow control switch will return to ambient conditions within a few seconds.
- To begin operation, press the ON/OFF power switch on the Riptide™ Aspiration Pump control panel and confirm that the power switch button lights, the pump motor starts and produces a steady hum.
- Allow it to run for at least one minute. Confirm normal operation and the presence of vacuum as indicated on the gauge.
- Using the vacuum control valve on the Riptide™ Aspiration Pump, adjust the vacuum to a reading of minimum 20 inHg (68 kPa) but not exceeding 25 inHg (85 kPa) on the gauge. Adjust the vacuum by rotating the Vacuum Control Valve. To increase the vacuum, turn the dial clockwise. To decrease the vacuum, turn the dial counter-clockwise (anti-clockwise).
- Note that it is normal for the indicator needle of the gauge to oscillate or vibrate in response to pump pulsation. Allow the range of the needle to stabilize and adjust the vacuum control so that the midpoint of the motion aligns with the desired setting.
- The Riptide™ Aspiration System is now ready to aspirate.
- During the procedure, monitor the vacuum level indicated on the gauge. It is normal for the needle to drift about the desired set point as use conditions change. The vacuum level may drop as a result of turning the Aspiration Tubing flow control switch on, opening a tubing connection or exchanging a catheter. The vacuum level will recover to its set point when the flow control switch is returned to OFF or when the tubing or catheter connection is restored.
- During the procedure, monitor the fluid level that may have collected in the canister. It is recommended that the fluid not be allowed to fill more than about 75% of the capacity. Should this occur, the physician should have the Riptide™ Collection Canister with Intermediate Tubing changed out.
- At the conclusion of the aspiration procedure, turn off the Riptide™ Aspiration Pump by pressing the ON/OFF power switch. The green light on the switch will go out and the pump will stop producing a humming noise.
- The Arc™ Catheter, React™ 68 Catheter, React™ 71 Catheter, Riptide™ Aspiration Tubing, Riptide™ Large Bore Aspiration Tubing, and Riptide™ Collection Canister with Intermediate Tubing are single use only. Remove and discard in accordance with standard biological waste disposal procedures in effect.
- Disconnect the power cord from the mains.

CLEANING

- Place the attached tethered cap over the vacuum inlet prior to cleaning.
- Disconnect the power cord from the pump and clean separately if required.

- The outside of the Riptide™ Aspiration Pump enclosure may be cleaned by wiping down with 70% IPA and common non-bleach, non-solvent, clinical surface cleaning agents, for example Diversey Virex Tb (ready-to-use) or equivalent. Wipe dry before storage.
- Do not use cleaning agents containing petroleum base solvents, acids, caustics, or chlorinated solvents.
- The Riptide™ Aspiration Pump is not compatible with any sterilization procedures including ETO, e-beam, gamma, and autoclave.
- Do not attempt to disassemble the pump other than removing the cord and Riptide™ Collection Canister with Intermediate Tubing.
- Do not immerse the Riptide™ Aspiration Pump in water or cleaning solutions, or use a flooding rinse as a cleaning method.
- Do not inject, spray or otherwise introduce water, IPA, or cleaning agents into the cooling air intake louvers or exhaust vents located on the bottom.
- Never inject, spray, aspirate, or otherwise introduce cleaning or decontamination agents into the vacuum inlet. The pump is designed only for air contact and the introduction of any liquids or solids will cause non-repairable damage to internal components.
- If the Riptide™ Aspiration Pump is known to have ingested fluids during a procedure it should be considered as contaminated and treated in accordance with standard biological waste procedures in effect. No approved cleaning methods exist for internal decontamination.

STORAGE

- Place the tethered cap over the vacuum inlet to prevent entry of dust and other contaminants.
- The Riptide™ Aspiration Pump may be stored in a clean warehouse or storeroom commonly used for clinical and lab supplies. See characteristics below for environmental limits.
- The pump does not have an applicable "Use-by date". However, after extended storage it is recommended that it be cleaned, examined for damage, and tested for basic functionality prior to its introduction in to a clinical setting.

TROUBLESHOOTING

- No user serviceable parts are inside the pump. Do not modify the pump or open the enclosure.
- Use the troubleshooting chart below to determine common causes and recommended remedies.
- Riptide™ Aspiration Pump Fuses – replace only with exact equivalent F 5A H 250V, UL listed 5 x 20 mm.

PROBLEM	POSSIBLE CAUSE	ACTION
Pump has mechanical damage to enclosure, gauges, controls	Improper handling, dropping, mechanical damage	Replace pump
Power cord or a plug on the cord damaged	Improper handling, misuse, mechanical damage	Cord may be replaced with a suitable length hospital grade or equivalent single unit meeting specifications: Mains plug: As required by site region, earthing connection required Cable: EN50525/IEC60227, integral earthing conductor required Rating: 250V, 10A Appliance socket: IEC60320-C13 Do not use plug adapters or power converters not certified to meet IEC60601-1 and IEC60601-1-2.
Power connection on pump enclosure damaged	Improper handling, misuse, mechanical damage	Replace pump
Pressing ON power switch causes mains breaker to trip or mains fuse to blow	Internal electrical failure	Replace pump
ON power switch does not light when pushed, pump does not run	Mains power not connected	Plug pump into receptacle
	Cord not connected to appliance power inlet	Plug cord into enclosure's appliance power inlet plug
	Loose cord at back of unit	Press in or adjust cord in back of enclosure
	Bad power cord	Replace power cord
	Mains power source is bad or incorrect voltage	Plug pump into correct receptacle
	Pump fuse blown	Replace fuse(s) Use only exact equivalent. F 5A H250V, UL listed 5 x 20 mm.
	Mains supply breaker not on or mains fuse blown	Turn on mains supply or replace fuse
	On power switch not pushed hard enough	Press again
	Internal mechanical or electrical failure	Replace pump
ON power switch does not light but pump starts and appears operating normally	Faulty ON power switch	Complete procedure if required but replace pump at first opportunity
ON power switch lights when pushed but pump makes no noise	Internal electrical failure or faulty ON power switch	Replace pump
ON power switch lights and pump starts briefly but switch does not remain depressed	Faulty ON power switch	Replace pump
ON power switch lights when pushed and cooling fan on bottom runs but pump does not run	Overheated motor due to operation at full load for an extended period or blocked cooling vents	Turn pump off and allow time to cool down. Remove any absorbent padding or plastic sheeting blocking pump air vents.
	Pump contaminated by aspiration overflow	Replace pump. Units contaminated with bio fluids should be disposed of in accordance with standard hospital biohazard procedures.
	Internal mechanical or electrical failure	Replace pump
Pump runs but has abnormal operation: unusually loud high vibration running very hot burning smell, smoke	Pump rocking - not sitting on level surface with all 5 supporting feet	Re-position pump on flat, rigid, horizontal surface
	Cooling air intake and/or bottom exhaust is blocked	Re-position pump. Do not place pump on plush absorbent padding or cover with splash sheeting.
	Pump contaminated by overflow	Replace pump. Units contaminated with bio fluids should be disposed of in accordance with standard hospital biohazard procedures.
	Pump connected to improper mains voltage supply	Replace pump with unit that matches mains power input
	Internal electrical or mechanical damage or failure	Replace pump
Gauge needle vibrates excessively	Vacuum pressure set too low – especially below 15 inHg (51 kPa).	Increase vacuum between 20-25 inHg (68-85 kPa). It is normal for the indicator needle of the gauge to oscillate or vibrate in response to pump pulsation, especially at minimal vacuums. Allow the range of the needle to stabilize and adjust the vacuum control so that the midpoint of the motion aligns with the desired setting.
	Faulty gauge if needle does not stabilize at full vacuum.	Procedure may be continue at physicians discretion but replace pump at first opportunity
Gauge needle indicates vacuum greater than 30 inHg (102 kPa) or is pegged fully anti-clockwise when running	Faulty or damaged gauge.	Use vacuum control valve to attempt to set vacuum to recommended range of 20-25 inHg (68-85 kPa). Procedure may be continue at physicians discretion but replace pump at first opportunity
Pump runs but no or low vacuum indicated at gauge, vacuum may be present at Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing	Vacuum control valve not adjusted	Adjust valve to set vacuum to desired level
	Faulty gauge	Use vacuum control valve to attempt to set vacuum to recommended range of 20-25 inHg (68-85 kPa). Procedure may be continue at physicians discretion but replace pump at first opportunity
	Flow control switch on Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing not set correctly	Adjust flow control switch to OFF
	Pump contaminated by overflow, pump seizing	Replace pump
	Internal electrical or electrical damage or failure	Replace pump
Pump runs with vacuum indicated at gauge, but no vacuum at Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing distal end	Loose, leaking, or missing Intermediate Tubing	Install tubing correctly and check fittings
	Flow control switch in OFF position	Move switch to ON position
	Riptide™ Collection Canister lid loose or drain port open	Tighten lid, close port with tethered cap
	Riptide™ Collection Canister not vertical and secured in Riptide™ Aspiration Pump receptacle	Turn off the Riptide™ Aspiration Pump and place the Riptide™ Collection Canister in the receptacle, and restart the Riptide™ Aspiration Pump
	Riptide™ Collection Canister bio-filter plugged	Replace the Riptide™ Collection Canister. Do not attempt to clean or bypass filter.
	Plugged or kinked tubing	Straighten or replace tubing
	Broken canister, defective connector or vacuum tubing	Replace with a new Riptide™ Collection Canister with Intermediate Tubing and Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing
	Riptide™ Collection Canister full or foaming. Overflow protection valve has activated and stopped flow	Replace the Riptide™ Collection Canister. Do not attempt to bypass overflow valve.
	Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing flow control switch set incorrectly	Set flow switch to desired setting
	Defective or broken Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing flow control switch	Replace the Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing
Pump runs but low suction or insufficient vacuum in Catheter	Loose, leaking, or missing Intermediate Tubing	Install tubing and check fittings
	Loose canister lid, vacuum leak	Reposition and press lid closed
	Canister dump/vent port is open or leaking	Close dump/vent port with tethered cap on lid
	Pinched or kinked connector or suction tubing	Straighten connector or suction tubing
	Incorrect vacuum control valve setting	Adjust vacuum control valve to proper setting
	Incorrect flow control switch setting	Adjust flow control switch to proper setting – OFF to build vacuum, ON to direct vacuum to catheter
	Flow control switch on tubing defective	Replace the Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing
	Canister bio filter is clogged or overflow valve is closed	Replace the Riptide™ Collection Canister. Do not attempt to clean or bypass filter.
	Vacuum leak internal to pump enclosure	Replace pump

PROBLEM	POSSIBLE CAUSE	ACTION
	Canister is full and overflow protection working normally	Replace the Riptide™ Collection Canister. Do not attempt to clean or bypass canister. Dispose of full canister in accordance with standard hospital biohazard procedures.
	Pump contaminated by canister overflow or liquid ingress from previous procedure	Replace pump. Do not attempt to clean or decontaminate pump. Pump units contaminated with bio fluids should be disposed of in accordance with standard hospital biohazard procedures.
Vacuum indicated on gauge does not respond to change in vacuum control setting	Faulty vacuum control knob or faulty vacuum gauge	Replace pump
	Internal electrical or mechanical damage or failure	Replace pump
Pump spontaneously stops running or is intermittent during use	Loss of mains power, breaker interruption, power surge, brownout	Restore mains power or connect to uninterruptable power supply.
	Power cord disturbed, loose	Re-plug power cord securely to mains and pump enclosure
	Blown Riptide™ Aspiration Pump fuse	Replace fuse(s) Use only exact equivalent F 5A H 250V, UL listed 5 x 20 mm.
	Pump overheated due to long continuous running in poor cooling	Allow pump to cool, correct cooling air flow blockage, and restart
	Riptide™ Collection Canister overflowed and fluid ingress has seized pump	Replace Riptide™ Aspiration Pump and Riptide™ Collection Canister
	Attempted use of non-validated canister without filters; fluid ingress causing pump to seize	Replace Riptide™ Aspiration Pump. Use correct Riptide™ Collection Canister Pump may be biological hazard
	Incorrect tubing connection for the Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing connected directly to vacuum inlet of the Riptide™ Aspiration Pump bypassing the Riptide™ Collection Canister	Replace pump. Pump may be biological hazard
	Internal electrical or mechanical damage or failure	Replace pump
Pump does not shut off when switch is pushed	Switch not pushed hard enough	Press again
	Faulty switch or internal electrical failure	Pull mains plug to un-power. Replace pump
Riptide™ Collection Canister does not fit in the receptacle of the Riptide™ Aspiration Pump	Attempted use of non-validated canister system.	Replace with Riptide™ Collection Canister with Intermediate Tubing
Tubing does not fit correctly on Riptide™ Aspiration Pump vacuum inlet	Attempted use of non-validated canister and/or tubing	Replace with Riptide™ Collection Canister with Intermediate Tubing
	Attempted connection of the Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing directly to the vacuum inlet of the Riptide™ Aspiration Pump	Review the Riptide™ Aspiration System *Instructions for Use*. Install the Riptide™ Collection Canister and connect the Riptide™ Aspiration Tubing or Riptide™ Large Bore Aspiration Tubing to the port labeled "PATIENT" on the Riptide™ Collection Canister.

MAINTENANCE

- Operating life: The Riptide™ Aspiration Pump has an operating life of 500 hours.
- The enclosure does not contain any user serviceable parts inside and should not be opened.
- Fuses: Located at the back of the unit. Replace only with exact equivalent F 5A H 250V, UL listed 5 x 20mm.
- Sterilization: The Riptide™ Aspiration Pump is NOT designed to be sterilized by autoclaving, chemical means (such as ETO and other sterilant compounds), or radiation. Any attempt to do so will cause non-repairable damage to the unit.

DISPOSAL

- Riptide™ Aspiration Pump with mechanical/electrical failure or normal wear-out: Dispose of non-functioning pumps in accordance with standard hospital procedures for electromechanical equipment.
- Riptide™ Aspiration Pump with contamination by aspirated fluid ingress: Dispose of in accordance with standard hospital biohazard procedures.
- The Arc™ Catheter, React™ 68 Catheter, React™ 71 Catheter, Riptide™ Aspiration Tubing, Riptide™ Large Bore Aspiration Tubing and Riptide™ Collection Canister with Intermediate Tubing are single use only. Dispose of in accordance with standard hospital biohazard procedures.

CHARACTERISTICS

Characteristic	Value
Model	Riptide™ Aspiration Pump MAP-1000EU
Vacuum Range, Nominal (at sea level)	0-29 inHg (0-98 kPa)
Vacuum Gauge	+/- 5% of full scale value
Flow Rate, Nominal (at sea level)	50Hz: 0-0.66 SCFM (0-19 LPM) 60Hz: 0-0.80 SCFM (0-23 LPM)
Power Input Rating	220-240VAC, 50/60Hz, 200VA max.
Overcurrent Protection (Fuses)	F 5A H 250V, UL listed 5 x 20mm
Approximate Dimensions	Length – 16.1in (40.9cm) Depth – 13.2in (33.5cm) Height – 12.3in (31.2cm)
Weight	Approximately 23lbs (10kg)
Duty Cycle	Non-continuous 97% (58.2 minutes on, 1.8 minutes off)
Operating Conditions (unpowered)	Temperature: 65 to 75˚F (18 to 24˚C) Humidity 20-80% non-condensing Air pressure: 24-31 inHg (81-105 kPa)
Storage Conditions	Temperature: -25 to 125˚F (-32 to 52˚C) Humidity: 5-90% non-condensing Air pressure: 20-31 inHg (68-105 kPa), safe in standard pressurized cargo air transport
Enclosure Ingress Rating	IP21 (Drip Tight)

ELECTRICAL SAFETY

General	IEC60601-1:2012 General standard, Medical devices
Earthbond	IEC60601-1:2012 0.2 ohm max.
Leakage Current	IEC60601-1:2012 Type BF, Class I Medical Equipment

ELECTROMAGNETIC COMPATIBILITY

The Riptide™ Aspiration Pump is expected to be relatively unaffected by common electromagnetic (EM) disturbances. In the event of unusual or extraordinary EM events beyond the limits, it is possible that device may exhibit a loss of Essential Performance (the ability to generate the necessary vacuum required for aspiration as set by the user). Should this occur, discontinue use of the device. The Riptide™ Aspiration Pump is intended for use in electromagnetic environments as specified below.

Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Riptide™ Aspiration Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should make sure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Riptide™ Aspiration Pump may use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Riptide™ Aspiration Pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Complies	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Riptide™ Aspiration Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	The Riptide™ Aspiration Pump should not be affected by electrostatic discharge that might occur under normal conditions of use. It is recommended that floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Complies	Mains power quality should be similar to that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Complies	Mains power quality should be similar to that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 seconds	Complies	Mains power quality should be similar to that of a typical commercial or hospital environment. When the user of the Medical Electrical Equipment continued function also calls in the event of disruption of supply, it is recommended the EUT from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	Complies	Mains power quality should be similar to that of a typical commercial or hospital environment.

NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*

			Portable and mobile RF communications equipment should be used no closer to any part of the Riptide™ Aspiration Pump than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3V rms 150 kHz to 80 MHz	Complies	Recommended separation distance
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 6 GHz	Complies	$d = 1.2\,P\sqrt{}$ 80 MHz-800 MHz $d = 2.3\,P\sqrt{}$ 800 MHz-6 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: *At 80 MHz and 800 MHz, the higher frequency range applies.*
NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.*

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Riptide™ Aspiration Pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the pump or the transmitting device from which it is receiving signals.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Riptide™ Aspiration Pump

This section provides information on the recommended separation distance between portable and mobile RF communications equipment and the Riptide™ Aspiration Pump. The Riptide™ Aspiration Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the pump users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to the Frequency of Transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 6 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1*: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*
NOTE 2*: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.*

LIMITED WARRANTY

Although this product has been manufactured under carefully controlled conditions, the manufacturer has no control over the conditions under which this product is used. The manufacturer therefore disclaims all warranties, both expressed and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. The manufacturer shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind the manufacturer to any representation or warranty with respect to the product. The exclusions and limitation set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

Symbol Glossary

Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Caution
	Refer to instruction manual/booklet
	Keep dry
	Waste Electrical and Electronic Equipment Directive (WEEE, 2012/19/EU)
	Type BF Applied Part
IP21	Ingress Protection Marking (IP Code per IEC60529) Protection against vertically dripping water drops
EC REP	Authorized representative in the European Community
REF	Catalogue number
	Manufacturer
SN	Serial number

	Date of manufacture
CONTENTS	Contents of Package
	Non-sterile
	Equipotentiality
	Dangerous voltage
	Stand-by
	Variability, rotational adjustment
	UL Certification MEDICAL - GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HARZARDS ONLY IEC 60601-1 Edition 3.1 (2012)/EN 60601-1:2016 + A1:2013 + A12:2014 ANSI/AAMI ES 60601-1:A1: 2012, C1: 2009/(R) 2012 and A2: 2010/(R) 2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

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