Digitally signed by Poiata Vitalie
Date: 2019.02.18 15:54:10 IST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII **Nr.** 044322

Denumirea autorității de licențiere	**Camera de Licențiere**
Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență	**Societatea cu Răspundere Limitată "BIOSISTEM MLD"** mun.Chișinău, str. Albișoara, 16/1, ap. 7
Data și numărul certificatului de înregistrare de stat a titularului de licență	12.08.2010 MD 0101250
Numărul de înregistrare a întreprinderii sau IDNO	1010600028048
Codul fiscal	
Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența	*** Importul, comercializarea, asistența tehnică și reparația dispozitivelor medicale ***
Data eliberării licenței	4 octombrie 2010
Reperfectată: 1)19.10.2012; 2)14.05.2014	
Valabilă pînă la	4 octombrie 2015

Prelungită pînă la: 03.10.2020

Semnătura conducătorului autorității de licențiere

Director al Camerei de Licențiere

Valentin GUZNAC

L.Ș.

Notă: Licența este valabilă numai cu anexa autentificată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

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

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

Data 14. IAN. 2016
Nr. 03/2 – 19/23

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

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000002251429243**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

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

MD 0101250

„CAMERA ÎNREGISTRĂRII DE STAT" Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **14419** din **11.07.2016**

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.**
Modul de constituire: **nou creată.**
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, IDNP 0983103892591,
Asociați:
1. POIATA VITALIE , IDNP 0983103892591
cota 1803.60 lei, ce constituie 33,4 %
2. NASEDCHIN ALEXANDR , IDNP 2002001070747
cota 1798.20 lei, ce constituie 33,3 %
3. KOJEVNIKOV DMITRII , IDNP 0972305012362
cota 1798.20 lei, ce constituie 33,3 %.

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: 11.07.2016.

Specialist principal **Lazari Aliona**
tel. 022-266-252

A A 7 * E A * 0 3 7 0 4 3 1 E A

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

Lista fondatorilor Biosistem-mld SRL

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

Data primirii 27.03.2018 13:54:13

Anexe la SNC
"Prezentarea situaţiilor financiare"
Aprobat de Ministerul Finanţelor al Republicii Moldova

SITUAŢIILE FINANCIARE

pentru perioada 01.01.2017 31.12.2017

Entitatea BIOSISTEM MLD SRL
(Denumirea completă)

40717392 (Cod CUIIO)

1010600028048 (Cod IDNO)

Sediul: MD MD-2001 (Cod poştal) MUN.CHIŞINĂU; MUN.CHIŞINĂU SEC.RÎŞCANI
Raionul (municipiul, UTA); Localitatea
Albisoara, 16, 1, of.7
strada, nr, bl.

150 Cod CUATM

Activitatea principală: Comert cu ridicata al produselor farmaceutice

G4646 Cod CAEM, rev.2

Forma de proprietate: Proprietate privată

15 Cod CFP

Forma organizatorico-juridică: SOCIETATI CU RASPUNDERE LIMITATA

530 Cod CFOJ

Date de contact: Tel. +37322808719 e-mail biosistem.mld@gmail.com
WEB:

Numele şi coordonatele al contabilului-şef: Dl (dna) +37322808719
Tel. +37369463619

Unitatea de măsură: leu

Anexa 8

Notă informativă privind veniturile şi cheltuielile clasificate după natură

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vînzări	010	15.623.709	20.497.176
Alte venituri din activitatea operaţională	020		500
Venituri din alte activităţi	030	368.943	361.872
Total venituri (rd.010 + rd.020 + rd.030)	040	15.992.652	20.859.548
Variaţia stocurilor	050		
Costul vînzărilor	060	9.960.221	11.372.168
Cheltuieli privind stocurile	070	306.856	118.975
Cheltuieli cu personalul privind remunerarea muncii	080	129.850	169.200
Contribuţii de asigurări sociale de stat obligatorii şi prime de asigurare obligatorie de asistenţă medicală	090	35.709	46.530
Cheltuieli cu amortizarea şi deprecierea activelor imobilizate	100	7.389	90.494
Alte cheltuieli	110	306.855	548.183
Cheltuieli din alte activităţi	120	289.432	558.776
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	11.036.312	12.904.326
Profit (pierdere) pînă la impozitare (rd.040 – rd.130)	140	4.956.340	7.955.222
Cheltuieli privind impozitul pe venit	150	595.238	959.194
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160	4.361.102	6.996.028

Anexa 1

BILANŢUL

la 31.12.2017

Nr. crt.	ACTIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrşitul perioadei de gestiune
1	2	3	4	5
1.	**Active imobilizate**			
	Imobilizări necorporale	010	2.437	1.787
	Imobilizări corporale în curs de execuţie	020		
	Terenuri	030		
	Mijloace fixe	040	195.525	904.703
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investiţii financiare pe termen lung în părţi neafiliate	070		
	Investiţii financiare pe termen lung în părţi afiliate	080		
	Investiţii imobiliare	090		
	Creanţe pe termen lung	100		
	Avansuri acordate pe termen lung	110		
	Alte active imobilizate	120		
	Total active imobilizate (rd.010 + rd 020 + rd 030 + rd.040 + rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	197.962	906.490
2.	**Active circulante**			
	Materiale	140	2.329	457
	Active biologice circulante	150		
	Obiecte de mică valoare şi scurtă durată	160	49.454	63.968
	Producţia în curs de execuţie şi produse	170		
	Mărfuri	180	3.435.875	4.430.031
	Creanţe comerciale	190	5.303.786	3.157.174
	Creanţe ale părţilor afiliate	200		
	Avansuri acordate curente	210	793.582	1.097.547
	Creanţe ale bugetului	220	35.037	4.973
	Creanţe ale personalului	230		
	Alte creanţe curente	240		
	Numerar în casierie şi la conturi curente	250	747.829	4.742.040
	Alte elemente de numerar	260		
	Investiţii financiare curente în părţi neafiliate	270		
	Investiţii financiare curente în părţi afiliate	280		
	Alte active circulante	290	8.004	5.373
	Total active circulante (rd.140 + rd.150 + rd.160 + rd.170 + rd.180 + rd.190 + rd.200 + rd.210 + rd.220 + rd.230 + rd.240 + rd.250 + rd.260 + rd.270 + rd.280 + rd.290)	300	10.375.896	13.501.563
	Total active (rd.130 + rd.300)	310	10.573.858	14.408.053

Nr. crt.	PASIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrşitul perioadei de gestiune
1	2	3	4	5
3.	**Capital propriu**			
	Capital social şi suplimentar	320	5.400	5.400
	Rezerve	330		
	Corecţii ale rezultatelor anilor precedenţi	340	X	
	Profit nerepartizat (pierdere neacoperită) al anilor precedenţi	350	8.952.137	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	360	X	6.996.028
	Profit utilizat al perioadei de gestiune	370	X	
	Alte elemente de capital propriu	380		
	Total capital propriu (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)	390	8.957.537	12.645.055
4.	**Datorii pe termen lung**			
	Credite bancare pe termen lung	400		
	Împrumuturi pe termen lung	410		
	Datorii pe termen lung privind leasingul financiar	420		
	Alte datorii pe termen lung	430		
	Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)	440		
5.	**Datorii curente**			
	Credite bancare pe termen scurt	450		
	Împrumuturi pe termen scurt	460		
	Datorii comerciale	470	1.084.518	1.595.609
	Datorii faţă de părţile afiliate	480		
	Avansuri primite curente	490	186.214	7.303
	Datorii faţă de personal	500	7.343	45.149
	Datorii privind asigurările sociale şi medicale	510		
	Datorii faţă de buget	520	318.484	39.698
	Venituri anticipate curente	530		
	Datorii faţă de proprietari	540		
	Finanţări şi încasări cu destinaţie specială curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	19.762	75.239
	Total datorii curente (rd.450 + rd.460 + rd.470 + rd.480 + rd.490 + rd.500 + rd.510 + rd.520 + rd.530 + rd.540 + rd.550 + rd.560 + rd.570)	580	1.616.321	1.762.998
	Total pasive (rd.390 + rd 440 + rd.580)	590	10.573.858	14.408.053

Anexa 2

SITUAŢIA DE PROFIT ŞI PIERDERE

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vînzări	010	15.623.709	20.497.176
Costul vînzărilor	020	9.960.221	11.372.168
Profit brut (pierdere brută) (rd.010 – rd.020)	030	5.663.488	9.125.008
Alte venituri din activitatea operaţională	040		500
Cheltuieli de distribuire	050	208	202
Cheltuieli administrative	060	513.937	522.704
Alte cheltuieli din activitatea operaţională	070	272.514	350.476
Rezultatul din activitatea operaţională: profit (pier-dere) (rd.030 + rd.040 – rd.050 – rd.060 – rd.070)	080	4.876.829	8.152.126
Rezultatul din alte activităţi: profit (pierdere)	090	79.511	-196.904
Profit (pierdere) pînă la impoztare (rd.080 + rd.090)	100	4.956.340	7.955.222
Cheltuieli privind impozitul pe venit	110	595.238	959.194
Profit net (pierdere netă) al perioadei de gestiune (rd.100 – rd.110)	120	4.361.102	6.996.028

Anexa 3

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2017 pînă la 31.12.2017

Nr. d/o	Indicatori	Cod rd.	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrşitul perioadei de gestiune
1	2	3	4	5	6	7
1	**Capital social şi suplimentar**					
	Capital social	010	5.400			5.400
	Capital suplimentar	020				
	Capital nevărsat	030	0	0	0	0
	Capital neînregistrat	040				
	Capital retras	050	0	0	0	0
	Total capital social şi suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5.400			5.400
2	**Rezerve**					
	Capital de rezervă	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total reserve (rd.070 + rd.080 + rd.090)	100				
3	**Profit nerepartizat (pierdere neacoperită)**					
	Corecţii ale rezultatelor anilor precedenţi	110				
	Profit nerepartizat (pierdere neacoperită) al anilor precedenţi	120	8.952.137	4.361.103	7.669.613	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	130	X	6.996.028		6.996.028
	Profit utilizat al perioadei de gestiune	140	X	0	0	0
	Rezultatul din tranziţia la noile reglementări contabile	150				
	Total profit nerepartizat (pierdere neacoperită) (rd.110 + rd.120 + rd.130 + rd.140 + rd.150)	160	8.952.137	11.357.131	7.669.613	12.639.655
4	**Alte elemente de capital propriu, din care**	170				
	Diferenţe din reevaluare	171				
	Subvenţii entităţilor cu proprietate publică	172				
	Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180	8.957.537	11.357.131	7.669.613	12.645.055

Anexa 4

SITUAŢIA FLUXURILOR DE NUMERAR

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operaţională			
Încasări din vînzări	010	16.364.220	30.547.593
Plăţi pentru stocuri şi servicii procurate	020	18.057.882	1.242.716
Plăţi către angajaţi şi organe de asigurare socială şi medicală	030	165.559	205.235
Dobînzi plătite	040		
Plata impozitului pe venit	050	359.402	1.213.720
Alte încasări	060	2.173.630	
Alte plăţi	070	647.102	20.861.222
Fluxul net de numerar din activitatea operaţională (rd.010 – rd.020 – rd.030 – rd.040 – rd.050 + rd.060 – rd.070)	080	-692.095	7.024.700
Fluxuri de numerar din activitatea de investiţii			
Încasări din vînzarea activelor imobilizate	090		
Plăţi aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
Alte încasări (plăţi)	130		
Fluxul net de numerar din activitatea de investiţii (rd.090 – rd.100 + rd.110 + rd.120 + rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite şi împrumuturi	150		
Plăţi aferente rambursării creditelor şi împrumuturilor	160		
Dividende plătite	170	1.127.660	3.110.000
Încasări din operaţiuni de capital	180		
Alte încasări (plăţi)	190		
Fluxul net de numerar din activitatea financiară (rd.150 – rd.160 – rd.170 + rd 180 ± rd.190)	200	-1.127.660	-3.110.000
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	-1.819.755	3.914.700
Diferenţe de curs valutar favorabile (nefavorabile)	220	79.511	79.511
Sold de numerar la începutul perioadei de gestiune	230	2.488.073	747.829
Sold de numerar la sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	747.829	4.742.040

Anexa 6

Date generale

1. Certificat de înregistrare a entităţii, eliberat de Camera Înregistrării de Stat.
Număr de înregistrare MD0101250 Data înregistrării 12.08.2014 Seria MD Număr 0101250
2. Capital social înregistrat de Camera Înregistrării de Stat:
data 12.08.2010 ,suma 5.400 lei, inclusiv:
1) cota statului ——— lei,
2) cota deţinătorilor a cel puţin 20% ——— lei,
Modificări ulterioare:
a) ———, suma ——— lei, inclusiv cota statului ——— lei,
b) ———, suma ——— lei, inclusiv cota statului ——— lei,
3. Entităţile, activitatea cărora necesită licenţă, indică:
Licenţa în vigoare:
1) Număr 044322 ,data eliberării 2010-10-04 00:00:00
Termen de valabilitate 03.10.2020
Tipul de activitate ———
Organul care a eliberat licenţa ———
4. Numărul mediu scriptic al personalului în perioada de gestiune 3 persoane, inclusiv pe categorii:
1) personal administrativ 3 persoane,
2) muncitori ——— persoane,
5. Numărul personalului la 31.12.2017 3 persoane.
6. Remunerarea personalului entităţii în perioada de gestiune 169.200 lei.
7. Remunerarea membrilor organelor de administrare, de conducere şi supraveghere şi alte angajamente apărute sau asumate în legătură cu pensiile membrilor actuali sau ale foştilor membri ai acestor organe, pe categorii ——— lei
8. Avansurile şi creditele acordate membrilor organelor specificate la pct.7 ——— lei, inclusiv rambursate ——— lei.
9. Valoarea activelor imobilizate şi circulante, înregistrate în calitate de gaj[1]
1) valoarea de gaj ——— lei,
2) valoarea contabilă ——— lei.
10. Numărul acţiunilor ordinare la finele perioadei de gestiune ——— unităţi.
11. Profit net (pierdere netă) a perioadei de gestiune pentru o acţiune ordinară:
1) profit ——— lei,
2) pierdere ——— lei.
12. Dividende calculate pentru o acţiune ordinară pentru perioada de gestiune:
1) plătite ——— lei,
2) planificate pentru plată ——— lei.
13. Valută străină disponibilă, recalculată în monedă naţională a Republicii Moldova – total 849.462 lei, inclusiv (lei, denumirea şi codul valutei):
1) 698537 codul valutei Euro
2) 150925 codul valutei US Dollar
14. Numerar legat – total ——— lei.

În rîndurile, în care se înscriu sumele de gaj, în toate coloanele prin fracţie se reflectă:
a) la numărător – valoarea de gaj;
b) la numitor – valoarea contabilă

———

Anexa 7

Informatiile privind activele imobilizate

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Nr. rînd	Existenţa la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieşirea în cursul perioadei (la costul de intrare)	Existenţa la sfîrşitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrşitul perioadei	Deprecierea acumulată la sfîrşitul perioadei
1		2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuţie	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200	3.250	813				3.250	1.463	
2.1 brevete şi mărci	210								
2.2. licenţe de activitate	220	3.250	813				3.250	1.463	
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuţie	300								
4. Terenuri	400		X					X	
5. Mijloace fixe, total din care:	**500**	**205.204**	**9.679**		**796.422**	**6.100**	**995.526**	**90.823**	
5.1. clădiri	510								
5.2. construcţii speciale	520								
5.3. maşini, utilaje, instalaţii de transmisie	530	186.815	8.300		796.422	6.100	977.141	85.929	
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente şi inventar	550								
5.6. cesturi ulterioare aferente obiectelor neînregistrate în bilanţ	560								
5.7. mijloace fixe primite în leasing financiar	570								
5.8. mijloace fixe primite în gestiune economică	580								
5.9. alte mijloace fixe	590	18.385	1.379				18.385	6.894	
6. Resurse minerale	**600**								
7. Investiţii imobiliare, total	**700**								

Recipisa de primire a raportului

ID-ul raportului	289272
Tipul raportului	RSF1
Tipul perioadei de raportare	Anual
Anul de raportare	2017
Numărul de raportare a perioadei (număr)	10
Numărul de raportare a perioadei (text)	an
Codul statistic al organizaţiei	40717392
Codul fiscal al organizaţiei	1010600028048
IDNO organizaţiei	1010600028048
Denumirea organizaţiei	BIOSISTEM MLD SRL
Statutul raportului	Primit la BNS
Data creării raportului	26.03.2018 11:08:42
Data expedierii raportului	27.03.2018 13:54:13
Subdiviziunea teritorială a BNS	mun. Chişinău
Telefonul subdiviziunii teritoriale a BNS	0-22-739581

Таблицы финансового отчёта автоматически проверены на арифметические ошибки и логические связи между таблицами.

Контроль показателей на соответствие с предыдущим финансовым отчётом на данный момент НЕ выполнен.

Ответственность за правильность отражения экономических операций в бухгалтерском учёте и применённых методов учёта, а также за достоверность и полноту представленных данных и приложений несёт субъект и его ответственные лица, подписавшие финансовые отчёты.

Anexa nr.7 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. № A1906045 **din** от 08.02.2019

1. Destinatar / Получатель

Pentru participarea la proceduri de achizitii 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 localităţii** Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenţei restanţelor conform datelor Sistemului Informaţional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Автоматизированной Информационной Системы

La data emiterii prezentului certificat restanţa la bugetul public naţional constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 23.02.2019

5. Autentificarea organului fiscal / Подтверждение налогового органа

Sef. DOR Riscani
Funcţia/Должность

Semnătura/Подпись

Ana Stoicov
Numele şi prenumele/Фамилия и имя

L.Ş/ М.П.

Executor: Ujoan C
Numele şi prenumele/Фамилия и имя

MINISTERUL FINANŢELOR AL REPUBLICII MOLDOVA
IDNO 1006601001182
S7
SERVICIUL FISCAL DE STAT

Este extras din Sistemul Informaţional al SFS SIA „Contul curent al contribuabilului"// 08.02.2019 ora 16:43:41
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (2,21)

ORDIN DE PLATA NR.: 48 TIP.DOC. 1

DATA EMITERII:18 februarie 2019

PLATITI: 16500-00 LEI: Sasesprezece Mii Cinci Sute lei 00 bani

PLATITOR: (R) 'BIOSISTEM MLD" SRL

CONTUL DE PLATI/CODUL IBAN
MD95ML000000002251429243
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau

CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R)Institutul de Cardiologie IMSP

CONTUL DE PLATI/CODUL IBAN
MD98ML000000002251902161
CODUL FISCAL :1003600150613 /

PRESTATORUL BENEFICIAR
BC"Moldindconbank"S.A.

CODUL BANCII:
:MOLDMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la licitatia publica nr. ocds-b-3wdp1-MD-1547470094945 si nr. ocds-b3wdp1-MD-1548676439476 din 19 febr 2019 si din 20 febr 2019

TIPUL TRANSFERULUI : NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:18/02/2019
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web "BIOSISTEM MLD" SRL Director

MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBEowggRGMIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTEQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxFzA

(semnatura electronica)

CONTABIL-SEF:Web "BIOSISTEM MLD" SRLContabil

MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowgY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKEx5NZWRlY29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAsT

L.S.

(semnatura electronica)

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe
Arizona
85281
USA

Holds Certificate No: **FM 92806**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The design, development, manufacture, and distribution of ePTFE Vascular Grafts with and without carbon, Balloon Expandable Stents, PTA Balloon Catheter, Percutaneous Catheters, Biopsy Needles and Instruments, Disposable Instruments and Breast Localization Wires, Cardiovascular Patches, Endoluminal Devices, Minimally Invasive Delivery Systems and related accessories, Cardiovascular Grafts, Fabrics, Felts, Pledgets, Shunts, Probes, Tapes, Pouches, Vena Cava Recovery Filters, Vena Cava Filter Recovery Cones, Delivery System products and Breast Tissue Markers, High Frequency Electronic Power Supplies and Catheters, Saline Injectors and Inflation Devices.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 01/05/2005 Effective Date: 09/16/2016 Expiry Date: 02/28/2019

CMDCAS Recognized Registrar

SCC Accredited CB-MS OCSM Accrédité CCN

...making excellence a habit.™

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

W.L. Gore & Associates, Inc.
1505 N. Fourth Street
Flagstaff
Arizona
86004
USA

Holds Certificate Number: MD 668305

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, development, manufacturing, labelling, packaging, boxing, storage, customer service, steam sterilization, validation and routine control of Ethylene Oxide sterilization per EN ISO 11135-1, distribution and delivery of Vascular grafts, Heparin coated vascular grafts, Heparin coated vascular endoprosthesis and delivery systems, Vascular endoprosthesis and delivery systems, Intrahepatic and biliary endoprosthesis and delivery systems, Surgical membrane products, Cardiovascular patches, soft tissue patches, Septal Defect Closure Device, Staple Line Reinforcement Material, Introducer Sheath, Intravascular Balloon catheter, Embolic Filter, Heparin coated vascular stent and delivery system, Intravascular device for removal of organized emboli and thrombi and Suture with and without pledgets.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-04-27
Latest Revision Date: 2017-11-13

Effective Date: 2017-11-16
Expiry Date: 2019-02-28

...making excellence a habit.™

Certificate No: MD 668305

Location	Registered Activities
W.L. Gore & Associates, Inc. Medical West 1505 North Fourth Street Flagstaff Arizona 86004 USA	Design, development, and manufacturing of medical devices as listed in scope expression.
W.L. Gore & Associates, Inc. Medical Central 1500 N. Fourth Street Flagstaff Arizona 86004 USA	Design, development, manufacturing, and steam sterilization of medical devices as listed in scope expression.
W.L. Gore & Associates, Inc. Echo Ridge 3250 W. Kiltie Lane Flagstaff Arizona 86005 USA	Design, development, and manufacturing of medical devices as listed in scope expression. Testing Center.
W.L. Gore & Associates, Inc. Fisher Point 4000 W. Kiltie Lane Flagstaff Arizona 86005 USA	Packaging, Boxing, Distribution, Validation and routine control of sterilization by Ethylene Oxide, according to the standard EN ISO 11135-1, for medical devices as listed in scope expression.
W.L. Gore & Associates, Inc. Kendrick Peak 4250 W. Kiltie Lane Flagstaff Arizona 86005 USA	Design, development, and manufacturing of medical devices as listed in scope expression.

Original Registration Date: 2017-04-27

Latest Revision Date: 2017-11-13

Effective Date: 2017-11-16

Expiry Date: 2019-02-28

Certificate No: MD 668305

Location	Registered Activities
W.L. Gore & Associates, Inc. Woody Mountain 3750 W. Kiltie Lane Flagstaff Arizona 86005 USA	Materials warehousing for medical devices as listed in scope expression.
W.L. Gore & Associates, Inc. Woody Springs 3450 W. Kiltie Lane Flagstaff Arizona 86005 USA	Design, development, and manufacturing of medical devices as listed in scope expression.
W.L. Gore & Associates, Inc. Phoenix 1 32360 N. North Valley Pkway Phoenix Arizona 85085 USA	Design, development, and manufacturing of medical devices as listed in scope expression.
W.L. Gore & Associates, Inc. Phoenix 2 32470 N. North Valley Pkway Phoenix Arizona 85085 USA	Design, development, and manufacturing of medical devices as listed in scope expression.
W.L. Gore & Associates, Inc. Phoenix 3 32320 N. North Valley Pkway Phoenix Arizona 85085 USA	Design, development, manufacturing and materials warehouse for medical devices as listed in scope expression.

Original Registration Date: 2017-04-27
Latest Revision Date: 2017-11-13

Effective Date: 2017-11-16
Expiry Date: 2019-02-28

Certificate No: MD 668305

Location	Registered Activities
W.L. Gore & Associates, Inc. Appleton Central 301 Airport Road Elkton Maryland 21921 USA	Design, development, manufacturing, labeling, packaging, boxing, steam sterilization process, testing center, materials warehouse, and distribution for medical devices as listed in scope expression.
W.L. Gore & Associates, Inc. Medical East 1500 N. Fourth Street Flagstaff Arizona 86004 USA	Design and development of medical devices as listed in scope expression.
W.L. Gore & Associates, SARL European Customer Service Center (ECSC) Ciutat de Granada 178 08018 Barcelona Spain	European Customer Service and Distribution of GORE Medical Products as listed in scope expression.
W.L. Gore & Associates, B.V. Gore European Warehouse Support (GEWS) Ringbaan Oost 152-a 5013 CE Tilburg The Netherlands	European Customer Service and Distribution of GORE Medical Products as listed in scope expression.
W.L. Gore & Associates (Pacific) Pte, Ltd. 83 Clemenceau Ave. #17-01, UE Square 239920 Singapore	Distribution of GORE Medical Products as listed in scope expression.
W.L. Gore & Associates, Inc. Silicon Valley 2890 De La Cruz Blvd Santa Clara California 95050 USA	Manufacturing, packaging, and boxing of medical devices as listed in scope expression.

Original Registration Date: 2017-04-27

Latest Revision Date: 2017-11-13

Effective Date: 2017-11-16

Expiry Date: 2019-02-28

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

DICHIARAZIONE DI CONFORMITÀ CE PER DISPOSITIVI MEDICI
EC Declaration of Conformity for medical devices

La sottoscritta
We, the undersigned

Sorin Group Italia S.r.l. Via Crescentino, sn – 13040 Saluggia (VC) - Italy

dichiara sotto la propria responsabilità che i prodotti sotto elencati
hereby declare under our sole responsibility that the products listed here below

Prodotto *Product*	Codice Prodotto *Product Code*	Classe *Class*
Carbomedics Carbo-Seal Aorto-Valvular Prosthesis	AP-021	III
Carbomedics Carbo-Seal Aorto-Valvular Prosthesis	AP-023	III
Carbomedics Carbo-Seal Aorto-Valvular Prosthesis	AP-025	III
Carbomedics Carbo-Seal Aorto-Valvular Prosthesis	AP-027	III
Carbomedics Carbo-Seal Aorto-Valvular Prosthesis	AP-029	III
Carbomedics Carbo-Seal Aorto-Valvular Prosthesis	AP-031	III
Carbomedics Carbo-Seal Aorto-Valvular Prosthesis	AP-033	III
Carbomedics Carbo-Seal Valsalva Aorto-Valvular Prosthesis	CP-021	III
Carbomedics Carbo-Seal Valsalva Aorto-Valvular Prosthesis	CP-023	III
Carbomedics Carbo-Seal Valsalva Aorto-Valvular Prosthesis	CP-025	III
Carbomedics Carbo-Seal Valsalva Aorto-Valvular Prosthesis	CP-027	III
Carbomedics Carbo-Seal Valsalva Aorto-Valvular Prosthesis	CP-029	III

sono conformi al tipo descritto nel Certificato di Esame del Tipo:
are conform to type described in the relevant EC Type Examination Certificate:

Annex III n° 24709 (rev. 1)

emesso da LNE/G-MED, 1 rue Gaston Boissier, 75724 PARIS CEDEX 15, FRANCE, Organismo Notificato n° 0459, secondo l'Allegato III della Direttiva Europea 93/42/CEE concernente i dispositivi medici e secondo la Direttiva Europea 2003/32/EC.
issued by LNE/G-MED, 1 rue Gaston Boissier, 75724 PARIS CEDEX 15, FRANCE, Notified Body n° 0459 according to Annex III of Directive 93/42/EEC concerning medical devices and according to Directive 2003/32/EC.

Sorin Group Italia S.r.l.
Sede Legale:
Via Benigno Crespi, 17 - 20159 Milano - Italy
Sede Amministrativa:
Via Statale 12 Nord, 86 - 41037 Mirandola (MO) Italy
Tel.+39 0535 29811 Fax +39 0535 25229
Stabilimento di Mirandola:
Via Statale 12 Nord, 86 - 41037 MIRANDOLA (MO) Italy
Tel.+39 0535 29811 Fax +39 0535 25229
Stabilimento di Saluggia:
Via Crescentino sn - 13040 SALUGGIA (VC) Italy
Tel. +39 0161 487.1 Fax +39 0161 487.681

Sedi Commerciali:
Via Statale 12 Nord, 86 - 41037 Mirandola (MO) Italy
Tel. +39 0535 29811- Fax +39 0535 25229
Via Benigno Crespi, 17 - 20159 Milano - Italy
Tel. +39 02 69465.211 - Fax +39 02 69465.300

Servizio Clienti Italia: +39 02 37014960
International Customer Service: +39 02 37027030

Capitale Sociale: € 8.550.034,00
Registro Imprese di Milano N. 10556980158
R.E.A. MILANO 1767776 - N.Mecc. Imp./Exp. MI 352423
Cod. Fisc. 10556980158 - Part. IVA 02109510368
ISO CODE IT02109510368
Registro Nazionale Produttori AEE N. IT08020000000823

Società soggetta all'attività di direzione e coordinamento da parte del capogruppo Sorin S.p.A.

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Si garantisce inoltre che i prodotti sopra indicati sono in accordo con tutti i requisiti applicabili delle citate Direttive.
It is also guaranteed that the indicated products meet all applicable provisions of the named Directives.

Questa dichiarazione è emessa sulla base del Certificato di Approvazione del Sistema di Garanzia della Qualità della Produzione:
This declaration is issued based on the Approval of Production Quality Assurance System Certificate:

Annex V n° 24692 (rev. 1)

emesso da LNE/G-MED, 1 rue Gaston Boissier - 75724 PARIS CEDEX 15, France, Organismo Notificato n°0459, in accordo con il punto 3 dell'Allegato V della Direttiva 93/42/CEE.
issued by LNE/G-MED, 1 rue Gaston Boissier - 75724 PARIS CEDEX 15, Notified Body n° 0459 according to section 3 of Annex V of the named Directive 93/42/EEC.

La presente DICHIARAZIONE DI CONFORMITÀ CE è valida per i dispositivi prodotti presso l'officina Cardiac Surgery sita in Saluggia (VC), Via Crescentino, sn – Italia e descritti nel Technical File TF-09.
This EC DECLARATION OF CONFORMITY is valid for the medical devices manufactured in the Cardiac Surgery facility of Saluggia (VC), Via Crescentino, sn – Italy and described in the Technical File TF-09.

Saluggia, 1st January 2013

Mauro Ercolani
Director, Regulatory Affairs
Sorin Group Italia S.r.l.

Sorin Group Italia S.r.l.
Sede Legale:
Via Benigno Crespi, 17 - 20159 Milano - Italy
Sede Amministrativa:
Via Statale 12 Nord, 86 - 41037 Mirandola (MO) Italy
Tel.+39 0535 29811 Fax +39 0535 25229
Stabilimento di Mirandola:
Via Statale 12 Nord, 86 - 41037 MIRANDOLA (MO) Italy
Tel.+39 0535 29811 Fax +39 0535 25229
Stabilimento di Saluggia:
Via Crescentino sn - 13040 SALUGGIA (VC) Italy
Tel. +39 0161 487.1 Fax +39 0161 487.681

Sedi Commerciali:
Via Statale 12 Nord, 86 - 41037 Mirandola (MO) Italy
Tel. +39 0535 29811- Fax +39 0535 25229
Via Benigno Crespi, 17 - 20159 Milano - Italy
Tel. +39 02 69465.211 - Fax +39 02 69465.300

Servizio Clienti Italia: +39 02 37014960
International Customer Service: +39 02 37027030

Capitale Sociale: € 8.550.034,00
Registro Imprese di Milano N. 10556980158
R.E.A. MILANO 1767776 - N.Mecc. Imp./Exp. MI 352423
Cod. Fisc. 10556980158 - Part. IVA 02109510368
ISO CODE IT02109510368
Registro Nazionale Produttori AEE N. IT08020000000823

Società soggetta all'attività di direzione e coordinamento da parte del capogruppo Sorin S.p.A.

DECLARATION OF CONFORMITY

Medical Devices

We hereby declare that the distributed CE marked products:

Bard® Fabrics, Felts, Pledgets, Tapes, and Pouches:

Fabrics - Class III

Felts - Class III

Pledgets - Class III

Tapes - Class III

Bard® Parsonnet™ Pulse Generator Pouches - Class IIb

as specified in the annexed Surgical Fabrics Product List, comply with Annex II of the EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

These products are covered by the Full Quality Assurance EC certificate # CE01467 dated December 22, 2006 and first issued on December 5, 1996 by BSI Product Services (Notified Body Number 0086) and the Design Examination Certificate # CE87585 dated 27 January, 2005. The address of the EU Authorized Representative is Bard Limited, Crawley, UK RH11 9BP.

This Declaration of Conformity covers the products specified above, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

Bard Peripheral Vascular, Inc.
P.O. Box 1740
1625 West 3rd Street
Tempe, AZ 85280-1740

Issued at, and under the sole responsibility of,
Bard Peripheral Vascular, Inc.
Tempe, Arizona on October 25, 2007.

John Van Vleet
Vice President, Regulatory and Clinical Affairs

Bard® Fabrics
Class III

Item Number	Specials	Product Name	Size (metric)	Size (English)
007942		Bard® Sauvage® Filamentous Fabric	2.5 cm x 10.2 cm	1" x 4"
007943		Bard® Sauvage® Filamentous Fabric	5.1 cm x 5.1 cm	2" x 2"
007944		Bard® Sauvage® Filamentous Fabric	5.1 cm x 10.2 cm	2" x 4"
007828		Bard® Sauvage® Filamentous Fabric	10.2 cm x 10.2 cm	4" X 4"
007829		Bard® Sauvage® Filamentous Fabric	15.2 cm x 15.2 cm	6" X 6"
007940		Bard® Sauvage® Filamentous Fabric	1 cm x 15.2 cm	3/8" x 6"
007937		Bard® DeBakey® Double Velour Fabric	2.5 cm x 10.2 cm	1" x 4"
007939		Bard® DeBakey® Double Velour Fabric	5.1 cm x 10.2 cm	2" x 4"
007826		Bard® DeBakey® Double Velour Fabric	10.2 cm x 10.2 cm	4" X 4"
007827		Bard® DeBakey® Double Velour Fabric	15.2 cm x 15.2 cm	6" X 6"
	S16110001	Bard® DeBakey® Double Velour Fabric	1.9 cm x 2.5 cm	3/4" x 1"
	S16110002	Bard® DeBakey® Double Velour Fabric	27 cm x 36 mm	
	S16110003	Bard® DeBakey® Double Velour Fabric	2.2 cm x 3 cm	7/8" x 1 3/16"
007830		Bard® DeBakey® Elastic Knit Fabric	10.2 cm x 10.2 cm	4" X 4"
007831		Bard® DeBakey® Elastic Knit Fabric	15.2 cm x 15.2 cm	6" x 6"
	S16106002	Bard® DeBakey® Elastic Knit Fabric	5.1 cm x 5.1 cm	2" x 2"
007957		Bard® DeBakey® Woven Fabric	5.1 cm x 10.2 cm	2" x 4"
007955		Bard® DeBakey® Woven Fabric	10.2 cm x 10.2 cm	4" x 4"
007956		Bard® DeBakey® Woven Fabric	15.2 cm x 15.2 cm	6" x 6"
007979		Bard® Edwards Outflow Tract Fabric	5.1 cm x 10.2 cm	2" x 4"
007834		Bard® Edwards Outflow Tract Fabric	10.2 cm x 10.2 cm	4" x 4"
007835		Bard® Edwards Outflow Tract Fabric	15.2 cm x 15.2 cm	6" x 6"

Bard® Felts
Class III

Item Number	Specials	Product Name	Size (metric)	Size (English)
007975		Bard® PTFE Felt	1.3 cm x 10.2 cm	1/2" x 4"
007973		Bard® PTFE Felt	2.5 cm x 2.5 cm	1" x 1"
007968		Bard® PTFE Felt	2.5 cm x 10.2 cm	1" x 4"
007976		Bard® PTFE Felt	2.5 cm x 15.2 cm	1" x 6"
007974		Bard® PTFE Felt	6 mm x 5.1 cm	1/4" x 2"
007977		Bard® PTFE Felt	5.1 cm x 5.1 cm	2" x 2"
007836		Bard® PTFE Felt	10.2 cm x 10.2 cm	4" X 4"
007837		Bard® PTFE Felt	15.2 cm x 15.2 cm	6" X 6"
	S13075005	Bard® PTFE Felt	15.2 cm x 20.3 cm	6" X 8"
	S13075039	Bard® PTFE Felt	4 cm x 20 cm	
	S13075008	Bard® PTFE Felt	1.3 cm x 7.6 cm	1/2" x 3"
	S13075015	Bard® PTFE Felt	1.5 cm x 10.2 cm	
007018		Bard® PTFE Felt (Thick)	1 cm x 15.2 cm	3/8" x 6"
007019		Bard® PTFE Felt (Thick)	2.5 cm x 2.5 cm	1" x 1"
007958		Bard® PTFE Felt (Thick)	10.2 cm x 10.2 cm	4" x 4"
007959		Bard® PTFE Felt (Thick)	15.2 cm x 15.2 cm	6" X 6"
007021		Bard® Low Porosity PTFE Felt	2.5 cm x 2.5 cm	1" x 1"
007838		Bard® Low Porosity PTFE Felt	10.2 cm x 10.2 cm	4" x 4"
007839		Bard® Low Porosity PTFE Felt	15.2 cm x 15.2 cm	6" X 6"
	S13080001	Bard® Low Porosity PTFE Felt	2.5 cm x 2.5 cm	1" X 1"
	S13080003	Bard® Low Porosity PTFE Felt	2.5 cm x 7.6 cm	1" X 3"
008972		Bard® Polyester Felt	15.2 cm x 15.2 cm	6" X 6"
	S16077001	Bard® Polyester Felt	2.5 cm x 7.6 cm	1" X 3"
	S16077002	Bard® Polyester Felt	2.5 cm x 2.5 cm	1" X 1"
	S16077003	Bard® Polyester Felt	4 cm x 20 cm	

Bard® Pledgets
Class III

Item Number	Specials	Product Name	Size (metric)	Size (English)
007970		Bard® PTFE Felt Pledget (Rectangle)	4.8 mm x 6 mm	3/16 x 1 /4"
007963		Bard® PTFE Felt Pledget (Rectangle)	9.5 mm x 4.8 mm	3/8" x 3/16"
	S13075023	Bard® PTFE Felt Pledget (Rectangle)	5 mm x 1.5 cm	
	S13075012	Bard® PTFE Felt Pledget (Rectangle)	6 mm x 12.7 mm	1/4" x 1/2"
	S13075013	Bard® PTFE Felt Pledget (Rectangle)	9.5 mm x 12.7 mm	3/8" x 1/2"
	S13075017	Bard® PTFE Felt Pledget (Rectangle)	4.75 mm x 10 mm	
	S13075026	Bard® PTFE Felt Pledget (Rectangle)	4 mm x 6mm	5/32" x 1/4"
	S13075027	Bard® PTFE Felt Pledget (Rectangle)	6 mm x 4.8 mm	1/4" x 3/16"
007965		Bard® PTFE Felt Pledget (Square)	6 mm x 6 mm	1/4" x 1/4"
007972		Bard® PTFE Felt Pledget (Square)	7.9 mm x 7.9 mm	5/16" x 5/16"
	S13075029	Bard® PTFE Felt Pledget (Square)	3 mm x 3 mm	
	S13075038	Bard® PTFE Felt Pledget (Square)	6 mm x 6 mm	1/4" x 1/4"
007984		Bard® PTFE Felt Pledget (Round)	4.8 mm	3/16"
	S13075021	Bard® PTFE Felt Pledget (Round)	6 mm	1/4"
007969		Bard® PTFE Felt Pledget (Oval)	4.8 mm x 6 mm	3/16" x 1/4"
	S13075040	Bard® PTFE Felt Pledget (Oval)	9.5 mm x 7.9 mm	3/8" x 5/16"
007971		Bard® PTFE Felt Pledget, Thick (Round)	6 mm	1/4"
	007020	Bard® PTFE Felt Pledget, Thick (Round)	9.5 mm x 4.8 mm	3/8" x 3/16"
	S13075018	Bard® PTFE Donut/Pledget (2-piece Item)	Donut: 2.2 cm Pledget: 6mm x 6 mm	Donut: 7/8" Pledget: 1/4" x 1/4"

Bard® Tapes
Class III

Item Number	Specials	Product Name	Size (metric)	Size (English)
007913		Bard® PTFE Braided Tape	2 mm x 61 cm	1/16" x 24"
007914		Bard® PTFE Braided Tape	4 mm x 61 cm	3/16" x 24"
007917		Bard® PTFE Braided Tape	2 mm x 91.4 cm	1/16" x 36"
007918		Bard® PTFE Braided Tape	4 mm x 91.4 cm	3/16" x 36"
007915		Bard® Polyester Braided Tape	3 mm x 61 cm	1/8" x 24"
007916		Bard® Polyester Braided Tape	3 mm x 91.4 cm	1/8" x 36"

Bard® Pouches
Class IIb

Item Number	Specials	Product Name	Size (metric)	Size (English)
002904		Bard® Parsonnet™ Pulse Generator Pouch	Small	Small
002905		Bard® Parsonnet™ Pulse Generator Pouch	Large	Large
002906		Bard® Parsonnet™ Pulse Generator Pouch	X-Large	X-Large
	S16056001	Bard® Parsonnet™ Pulse Generator Pouch	Special	Special

EC Declaration of Conformity

Manufacturer:	*Edwards Lifesciences LLC* *One Edwards Way* *Irvine, CA 92614, USA*
European Representative:	*Dr. Robert Madjno* *Edwards Lifesciences Services GmbH* *Edisonstraße 6* *85716 Unterschleißheim, Germany*
Product category:	*07 – Non-active implantable devices* *(according to EN ISO 15225)*
Products:	***Biological Heart Valve Substitutes*** *Model codes, Names: see following pages*
Classification:	*Class III / Rules 8 and 17* *(According to Annex IX of the MDD)*
Conformity Assessment Route:	*Annex II*
UMDNS / GMDN Nomenclature:	*UMDNS: 15870 Prostheses, Cardiac Valve, Biological* *GMDN: 60242 Aortic Heart Valve Bioprosthesis* *60244 Mitral Heart Valve Bioprosthesis*
Applicable Standards:	*The harmonized standards and other consensus standards used (specified by numbers, titles, editions and/or dates of issue) in relation to which conformity is declared, as well as the identification of internal data confirming compliance are provided in the Essential Requirements Checklists for the products identified in this declaration.*
Start of CE Marking:	*See following pages*

We herewith declare that the distributed CE marked products specified above conform to the products covered by the "CE Marking of Conformity Certificate" issued and delivered by DEKRA Certification B.V., in accordance with Annex II of the "EC-Directive," Council Directive 93/42/EEC of 14 June 1993, concerning Medical Devices and with the particular requirements laid down in Annex I of Commission Regulation 722/2012 of 8 August, 2012, concerning medical devices manufactured utilising tissue of animal origin. All supporting documentation is retained at the premises of the manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directives that apply to them. This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification B.V.

The manufacturer has established and is maintaining a quality system which meets the requirements of the international standards indicated in the table below.

These directive(s) and standard(s) are supported by the following certificates:

Certificate Number	Valid until	Issued by	Holder of Certificate	Facility(ies)
3805474 ISO 13485:2003	2018-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	35 Changi North Crescent Singapore 499641 Singapore Altsagenstrasse 14, 6048 Horw, Switzerland 1212 Alton Parkway Irvine, CA 92606, USA
2103732CE04	2016-10-01	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 35 Changi North Crescent Singapore 499641 Singapore Altsagenstrasse 14 6048 Horw Switzerland Edisonstrasse 6 D-85716 Unterschleissheim Germany
2103732DE04	2016-10-01	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 35 Changi North Crescent Singapore 499641 Singapore Altsagenstrasse 14 6048 Horw Switzerland Edisonstrasse 6 D-85716 Unterschleissheim Germany
2103732DE08	2018-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 35 Changi North Crescent Singapore 499641 Singapore Altsagenstrasse 14 6048 Horw Switzerland Edisonstrasse 6 D-85716 Unterschleissheim Germany

Notified Body:

DEKRA Certification B.V
Meander 1051
6825 MJ Arnhem, The Netherlands
Identification Number 0344

This declaration of conformity is issued under the sole responsibility of Edwards Lifesciences LLC.

Signed for and on behalf of
Manufacturer:

Edwards Lifesciences LLC

Deborah Boxer June 22, 2015

Deborah Boxer
Sr. Manager, Regulatory Affairs

Trade Name and Sizes	Model(s)	Start of CE Marking
Carpentier-Edwards® PERIMOUNT® Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	2900	May 2000
Carpentier-Edwards® PERIMOUNT® Magna™ Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	3000 3000TFX	June 2002
Carpentier-Edwards® PERIMOUNT Plus® Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	6900P	May 2000
Carpentier-Edwards® PERIMOUNT Plus® Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	6900PTFX	April 2004
Carpentier-Edwards® PERIMOUNT Magna™ Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	7000TFX	Aug 2005
Carpentier-Edwards® PERIMOUNT® Magna Ease™ Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	3300TFX	Dec 2006
Carpentier-Edwards® PERIMOUNT® Magna Mitral Ease™ Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	7300TFX	Aug 2010
EDWARDS INTUITY™ Elite Valve [aortic] *Sizes: 19, 21, 23, 25, 27 mm*	8300AB	April 2014

Edwards

EC Declaration of Conformity

Manufacturer:	*Edwards Lifesciences LLC* *One Edwards Way* *Irvine, CA 92614, USA*
European Representative:	*Edwards Lifesciences Services GmbH* *Edisonstraße 6* *85716 Unterschleißheim, Germany*
Product category:	*07 – Non-active implantable devices* *(according to EN ISO 15225)*
Products:	***Biological Heart Valve Substitutes*** *Model codes, Names: see following pages*
Classification:	*Class III / Rules 8 and 17* *(According to Annex IX of the MDD)*
Conformity Assessment Route:	*Annex II*
UMDNS / GMDN Nomenclature:	*UMDNS: 15870 Prostheses, Cardiac Valve, Biological* *GMDN: 60242 Aortic Heart Valve Bioprosthesis* *60244 Mitral Heart Valve Bioprosthesis*
Applicable Standards:	*The harmonized standards and other consensus standards used (specified by numbers, titles, editions and/or dates of issue) in relation to which conformity is declared, as well as the identification of internal data confirming compliance are provided in the Essential Requirements Checklists for the products identified in this declaration.*
Start of CE Marking:	*See following pages*

We herewith declare that the distributed CE marked products specified above conform to the products covered by the "CE Marking of Conformity Certificate" issued and delivered by DEKRA Certification B.V., in accordance with Annex II of the "EC-Directive," Council Directive 93/42/EEC of 14 June 1993, concerning Medical Devices and with the particular requirements laid down in Annex I of Commission Regulation 722/2012 of 8 August, 2012, concerning medical devices manufactured utilising tissue of animal origin. All supporting documentation is retained at the premises of the manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directives that apply to them. This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification B.V.

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These directive(s) and standard(s) are supported by the following certificates:

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2103732CE04	2016-10-01	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 35 Changi North Crescent Singapore 499641 Singapore Altsagenstrasse 14 6048 Horw Switzerland Edisonstrasse 6 D-85716 Unterschleissheim Germany
2103732DE04	2016-10-01	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 35 Changi North Crescent Singapore 499641 Singapore Altsagenstrasse 14 6048 Horw Switzerland Edisonstrasse 6 D-85716 Unterschleissheim Germany
2103732DE08	2018-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 35 Changi North Crescent Singapore 499641 Singapore Altsagenstrasse 14 6048 Horw Switzerland Edisonstrasse 6 D-85716 Unterschleissheim Germany

Notified Body:	*DEKRA Certification B.V* *Meander 1051* *6825 MJ Arnhem, The Netherlands* *Identification Number 0344*

This declaration of conformity is issued under the sole responsibility of Edwards Lifesciences LLC.

Signed for and on behalf of Manufacturer:	*Edwards Lifesciences LLC*

Deborah Boxer 20 NOV 2015

Deborah Boxer
Sr. Manager, Regulatory Affairs

Trade Name and Sizes	Model(s)	Start of CE Marking
Carpentier-Edwards® PERIMOUNT® Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	2900	May 2000
Carpentier-Edwards® PERIMOUNT® Magna™ Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	3000 3000TFX	June 2002
Carpentier-Edwards® PERIMOUNT Plus® Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	6900P	May 2000
Carpentier-Edwards® PERIMOUNT Plus® Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	6900PTFX	April 2004
Carpentier-Edwards® PERIMOUNT Magna™ Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	7000TFX	Aug 2005
Carpentier-Edwards® PERIMOUNT® Magna Ease™ Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	3300TFX	Dec 2006
Carpentier-Edwards® PERIMOUNT® Magna Mitral Ease™ Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	7300TFX	Aug 2010
EDWARDS INTUITY™ Elite Valve [aortic] *Sizes: 19, 21, 23, 25, 27 mm*	8300AB	April 2014

LNE
Le progrès, une passion à partager

Certification
Médical-Santé
Notified Body N° 0459

ATTESTATION / *CERTIFICATE* **N° 24706 rev. 1**
Délivrée à Paris le 07 Octobre 2013
Issued in Paris on October 7th, 2013

ATTESTATION CE / *EC CERTIFICATE*

Examen de type / *Type Examination*
ANNEXE III de la Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX III Directive 93/42/EEC concerning medical devices

Fabricant / *Manufacturer*

SORIN GROUP ITALIA S.R.L.
Via Crescentino, sn
13040 SALUGGIA (VC) ITALY

Catégorie du(des) dispositif(s) / *Device(s) category*

Valves cardiaques mécaniques Sorin

Sorin mechanical heart valves

Identification du(des) dispositif(s) / *Identification of device(s)*

Bicarbon Fitline - Bicarbon Slimline - Bicarbon Overline (GMDN 43709)
(Voir addendum / see addendum)

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) P113431, un échantillon représentatif de la production est conforme aux exigences de l'annexe I de la Directive 93/42/CEE

LNE/G-MED certifies that, on the basis of the results contained in the file(s) referenced P113431, a representative sample of the production complies with the requirements of the Directive 93/42/EEC, annex I

Début de validité / *Effective date :* **October 7th, 2013 (included)**
Valable jusqu'au / *Expiry date :* **December 19th, 2016 (included)**

Laboratoire national de métrologie et d'essais LNE

For the General Director
Laurence DAGALLIER
Deputy Director

GMED_b3-V2-01-2013

LNE - 24706 rev. 1
Modifie le certificat 24706-0

LNE
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Certification
Médical-Santé

Addendum au certificat n°24706 rev. 1
Addendum of the certificate n°24706 rev. 1
Dossier / *File* N° P113431

Identification des dispositifs / *Identification of devices*

SORIN MECHANICAL HEART VALVES

Produit / *Product*	**Code produit /** *Product code*	**Classe du DM /** *Class DM*	**Code GMDN /** *GMDN code*
Bicarbon Fitline LFA Aortic	ICV0917 / ART19LFA	III	43709
Bicarbon Fitline LFA Aortic	ICV0918 / ART21LFA		
Bicarbon Fitline LFA Aortic	ICV0919 / ART23LFA		
Bicarbon Fitline LFA Aortic	ICV0920 / ART25LFA		
Bicarbon Fitline LFA Aortic	ICV0921 / ART27LFA		
Bicarbon Fitline LFA Aortic	ICV0922 / ART29LFA		
Bicarbon Fitline LFA Aortic	ICV0923 / ART31LFA		
Bicarbon Fitline LFM Mitral	ICV0924 / MTR19LFM		
Bicarbon Fitline LFM Mitral	ICV0925 / MTR21LFM		
Bicarbon Fitline LFM Mitral	ICV0926 / MTR23LFM		
Bicarbon Fitline LFM Mitral	ICV0927 / MTR25LFM		
Bicarbon Fitline LFM Mitral	ICV0928 / MTR27LFM		
Bicarbon Fitline LFM Mitral	ICV0929 / MTR29LFM		
Bicarbon Fitline LFM Mitral	ICV0930 / MTR31LFM		
Bicarbon Fitline LFM Mitral	ICV0931 / MTR33LFM		
Bicarbon Slimline LSA Aortic	ICV0934 / ART17LSA		
Bicarbon Slimline LSA Aortic	ICV0935 / ART19LSA		
Bicarbon Slimline LSA Aortic	ICV0936 / ART21LSA		
Bicarbon Slimline LSA Aortic	ICV0937 / ART23LSA		
Bicarbon Slimline LSA Aortic	ICV0938 / ART25LSA		
Bicarbon Slimline LSA Aortic	ICV0939 / ART27LSA		
Bicarbon Overline Aortic	ICV0870 / ART16LOV		
Bicarbon Overline Aortic	ICV0871 / ART18LOV		
Bicarbon Overline Aortic	ICV0872 / ART20LOV		
Bicarbon Overline Aortic	ICV0873 / ART22LOV		
Bicarbon Overline Aortic	ICV0874 / ART24LOV		

26 alinéas / *26 intended lines*

Site de fabrication / *Production Unit* :
Usine Cardiac Surgery de Sorin Group Italia S.r.l. / *Cardiac Surgery facility of Sorin Group Italia S.r.l.*

LNE/G-MED	0459

Laboratoire national de métrologie et d'essais • LNE

For the General Director
Laurence DAGALLIER
Deputy Director

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

N° 191 REGISTRO
DIR. SEGRET. 0,52
DIR. S.C. ....
RIMB. STAMP. ....

Ministero dell'Economia e delle Finanze
MARCA DA BOLLO
€16,00
SEDICI/00
Agenzia Entrate
00004165 00004749 WDJU7001
00023225 07/11/2013 16:04:16
4578-00010 8393961F770292EE
IDENTIFICATIVO : 01093569665691
0 1 09 356966 569 1

COMUNE DI SALUGGIA - PROVINCIA DI VERCELLI

Ai sensi del D.P.R. 28-12-2000, n. 445, art. 18 comma 2 e 3 si attesta che la presente copia □ parziale, ☒ totale composta di n. 6 fogli, è conforme all'originale a me esibito, ed è stata rilasciata previa ammonizione sulle responsabilità penali di cui all'art. 76

Saluggia, lì 14 FEB. 2014

L'UFFICIALE D'ANAGRAFE DELEGATO
(Angela Barbero)

COMUNE DI SALUGGIA (Prov. di Vercelli)

LNE
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Certification
Médical-Santé
Notified Body N° 0459

ATTESTATION / *CERTIFICATE* **N° 24707 rev. 6**
Délivrée à Paris le 28 janvier 2016
Issued in Paris on January 28th, 2016

ATTESTATION CE / *EC CERTIFICATE*

Examen de type / *Type Examination*
ANNEXE III de la Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX III Directive 93/42/EEC concerning medical devices

Fabricant / *Manufacturer*

SORIN GROUP ITALIA S.R.L.
Via Crescentino, sn
13040 SALUGGIA (VC) ITALY

Catégorie du(des) dispositif(s) / *Device(s) category*

Valves cardiaques prothétiques Carbomedics (CPHV)

Carbomedics prosthetic heart valves (CPHV)

Identification du(des) dispositif(s) / *Identification of device(s)*

Carbomedics Mechanical Bileaflet Heart Valves
(Voir addendum / see addendum)

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) P140835, un échantillon représentatif de la production est conforme aux exigences de l'annexe I de la Directive 93/42/CEE

LNE/G-MED certifies that, on the basis of the results contained in the file(s) referenced P140835, a representative sample of the production complies with the requirements of the Directive 93/42/EEC, annex I

Début de validité / *Effective date :* **January 31st, 2016 (included)**
Valable jusqu'au / *Expiry date :* **January 30th, 2021 (included)**

Laboratoire national de métrologie et d'essais LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

GMED_b3-V2-01-2013
LNE - 24707 rev. 6
Renouvelle le certificat 24707-5

LNE
Le progrès, une passion à partager

Certification
Médical-Santé

Addendum au certificat n° 24707 rev. 6
Addendum of the certificate n° 24707 rev. 6
Dossier / *File* N° P140835

Identification des dispositifs / *Identification of devices*

CARBOMEDICS MECHANICAL BILEAFLET HEART VALVES

Produit / *Product*	Code produit / *Product code*	Classe du DM / *Class DM*	Code GMDN / *GMDN code*
Carbomedics Standard Aortic	A5-016	III	60240
Carbomedics Standard Aortic	A5-018		
Carbomedics Standard Aortic	A5-019		
Carbomedics Standard Aortic	A5-021		
Carbomedics Standard Aortic	A5-023		
Carbomedics Standard Aortic	A5-025		
Carbomedics Standard Aortic	A5-027		
Carbomedics Standard Aortic	A5-029		
Carbomedics Standard Aortic	A5-031		
Carbomedics Standard Mitral	M7-016		60241
Carbomedics Standard Mitral	M7-018		
Carbomedics Standard Mitral	M7-021		
Carbomedics Standard Mitral	M7-023		
Carbomedics Standard Mitral	M7-025		
Carbomedics Standard Mitral	M7-027		
Carbomedics Standard Mitral	M7-029		
Carbomedics Standard Mitral	M7-031		
Carbomedics Standard Mitral	M7-033		
Carbomedics Reduced Aortic	R5-019		60240
Carbomedics Reduced Aortic	R5-021		
Carbomedics Reduced Aortic	R5-023		
Carbomedics Reduced Aortic	R5-025		
Carbomedics Reduced Aortic	R5-027		
Carbomedics Reduced Aortic	R5-029		

Laboratoire national de métrologie et d'essais • LNE

LNE/G-MED | **0459**

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

Produit / *Product*	**Code produit /** *Product code*	**Classe du DM /** *Class DM*	**Code GMDN /** *GMDN code*
Carbomedics Supra-Annular Aortic	S5-019	III	60240
Carbomedics Supra-Annular Aortic	S5-021		
Carbomedics Supra-Annular Aortic	S5-023		
Carbomedics Supra-Annular Aortic	S5-025		
Carbomedics Supra-Annular Aortic	S5-027		
Carbomedics Orbis Aortic	A1-019		
Carbomedics Orbis Aortic	A1-021		
Carbomedics Orbis Aortic	A1-023		
Carbomedics Orbis Aortic	A1-025		
Carbomedics Orbis Aortic	A1-027		
Carbomedics Orbis Aortic	A1-029		
Carbomedics Orbis Aortic	A1-031		
Carbomedics Orbis Mitral	M2-021		60241
Carbomedics Orbis Mitral	M2-023		
Carbomedics Orbis Mitral	M2-025		
Carbomedics Orbis Mitral	M2-027		
Carbomedics Orbis Mitral	M2-029		
Carbomedics Orbis Mitral	M2-031		
Carbomedics Orbis Mitral	M2-033		
Carbomedics Optiform Mitral	F7-021		
Carbomedics Optiform Mitral	F7-023		
Carbomedics Optiform Mitral	F7-025		
Carbomedics Optiform Mitral	F7-027		
Carbomedics Optiform Mitral	F7-029		
Carbomedics Optiform Mitral	F7-031		
Carbomedics Optiform Mitral	F7-033		

50 alinéas / *50 indented lines*

Site de fabrication / *Production Unit* :
Usine Cardiac Surgery de Sorin Group Italia S.r.l.
Cardiac Surgery facility of Sorin Group Italia S.r.l.

LNE/G-MED	0459

Laboratoire national de métrologie et d'essais • LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:

the Medical Devices Directive 93/42/EEC;

the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;

did (in accordance with Annex II clause 4 of the Directive) undertake an EC Design Examination on the stated products to ensure their conformity with the requirements of the Directive which apply to them. The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER: CryoLife, Inc.
1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, United States

PRODUCT NAME: BioGlue© Surgical Adhesive

PRODUCT DESCRIPTION: BioGlue Surgical Adhesive is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples. electrocautery, and/or patches) to bond, seal, and/or reinforce soft tissue.

DESIGN DOSSIER REFERENCE: document #TF00007.003, revision 003, dated 31 May 2017

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

Certificate No: 0088/094334/00050
Current Certificate: 1 December 2017
Expiry Date: 30 November 2022
Certificate Identity Number: 10039484
LRQA Notified Body Number: 0088

Original Approvals: 25 November 1997

Approval Certificate Number: MDD – 0015237

Chris Koci
Issued By: Lloyd's Register Quality Assurance Ltd

EC DESIGN EXAMINATION CERTIFICATE
CERTIFICATE 0949334 SUPPLEMENT

Certificate Identity Number: 10039484

CryoLife, Inc.

1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, United States

LRQA hereby confirms that the change(s) detailed below have been reviewed in conjunction with the approved Design Dossier and the EC Design Examination remains valid.

This supplement is only valid in association with the EC Design Examination certificate detailed above.

Supplement Number:	Supplement Date:	Details of amendment:
0	**21 November 2017**	**Renewal under jobs 1222716 & 1223002**

Certificate No: 0088/094334/00050
Current Certificate: 1 December 2017
Expiry Date: 30 November 2022
Certificate Identity Number: 10039484
LRQA Notified Body Number: 0088

Original Approvals: 25 November 1997

Chris Koci
Issued By: Lloyd's Register Quality Assurance Ltd

Lloyd's Register
LRQA

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

CryoLife, Inc.
1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144, USA

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No:	0949334/G
Original Approval:	December 19, 1995
Current Certificate:	January 1, 2017
Certificate Expiry:	December 31, 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

Lloyd's Register
LRQA

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE 0949334/G SCHEDULE

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

CryoLife, Inc.
1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144, USA

Class II Products:

BioGlue® Surgical Adhesive Delivery Devices
Applicator Tips
SolarGen 2100s Holmium: YAG Laser Delivery System
TMR 2000 Holmium: YAG Laser Delivery System

Class III Products:	EC Design Examination Certificate:
BioGlue® Surgical Adhesive Kits & Packs	0088/0949334/00050
BioFoam® Surgical Matrix	0088/0949334/00295
Sologrip III Handpiece Phoenix Handpiece Delivery System	0088/0949334/00336

Schedule Issue: 4

Date of Schedule Issue: January 1, 2017

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Management System of:

CryoLife, Inc.
1655 Roberts Boulevard NW
Kennesaw, Georgia 30144, USA

has been approved by Lloyd's Register Quality Assurance
to the following Management System Standards:

ISO 13485:2003
EN ISO 13485:2012

The Management System is applicable to:

Design and Manufacture of Implantable Medical Devices, Surgical Adhesives, Hemostasis Agents, Surgical Accessories, Surgical Laser Equipment Sterile Fiber Optic Delivery Systems for Transmyocardial Revascularization. Servicing of Surgical Laser Equipment. Processing and Distribution of Human Tissue.

This certificate forms part of the approval identified by certificate number UQA 0949334

Approval
Certificate No: UQA 0949334/A

Original Approval: May 29, 1998
Current Certificate: January 1, 2017
Certificate Expiry: March 1, 2019

Issued by: Lloyd's Register Quality Assurance, Inc. and for
and on behalf of Lloyd's Register Quality Assurance Limited

UKAS
MANAGEMENT
SYSTEMS
001

1330 Enclave Parkway, Suite 200, Houston, Texas 77077, USA
For and on behalf of LRQA Ltd. 1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5 17 09 01664 011

Manufacturer:

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product:

Heart Valves
Sorin Mechanical Heart Valves

The Certification Body of TÜV SÜD Product Service GmbH declares that a type examination has been carried out on the respective device type in accordance with MDD Annex III (4). This representative sample for the envisaged production conforms to the requirements of this Directive. For marketing of class III devices an additional Annex IV or V certificate is mandatory. For marketing of class IIb devices an additional Annex IV, V or VI certificate is mandatory. See also notes overleaf.

Report no.: 713114103

Valid from: 2017-10-17
Valid until: 2021-12-19

Date, 2017-10-16

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5 17 09 01664 011

Model(s):

Bicarbon Fitline
Bicarbon Slimline
Bicarbon Overline

Parameters:

Model Name	Product codes
Bicarbon Fitline LFA Aortic	ICV0917/ART19LFA
	ICV0918/ART21LFA
	ICV0919/ART23LFA
	ICV0920/ART25LFA
	ICV0921/ART27LFA
	ICV0922/ART29LFA
	ICV0923/ART31LFA
Bicarbon Fitline LFM Mitral	ICV0924/MTR19LFM
	ICV0925/MTR21LFM
	ICV0926/MTR23LFM
	ICV0927/MTR25LFM
	ICV0928/MTR27LFM
	ICV0929/MTR29LFM
	ICV0930/MTR31LFM
	ICV0931/MTR33LFM
Bicarbon Slimline LSA Aortic	ICV0934/ART17LSA
	ICV0935/ART19LSA
	ICV0936/ART21LSA
	ICV0937/ART23LSA
	ICV0938ART25LSA
	ICV0939/ART27LSA
Bicarbon Overline Aortic	ICV0870/ART16LOV
	ICV0871/ART18LOV
	ICV0872/ART20LOV
	ICV0873/ART22LOV
	ICV0874/ART24LOV

Facility(ies):

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn, 13040 Saluggia (VC), ITALY

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5 17 09 01664 012

Manufacturer:

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product: **Heart Valves**

The Certification Body of TÜV SÜD Product Service GmbH declares that a type examination has been carried out on the respective device type in accordance with MDD Annex III (4). This representative sample for the envisaged production conforms to the requirements of this Directive. For marketing of class III devices an additional Annex IV or V certificate is mandatory. For marketing of class IIb devices an additional Annex IV, V or VI certificate is mandatory. See also notes overleaf.

Report no.: 713114103

Valid from: 2017-10-17
Valid until: 2021-01-30

Date, 2017-10-16

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5 17 09 01664 012

Model(s): Carbomedics Mechanical Bileaflet Heart Valves

Parameters:

Model Name	Product codes
Carbomedics Standard Aortic	A5-016 A5-018 A5-019 A5-021 A5-023 A5-025 A5-027 A5-029 A5-031
Carbomedics Standard Mitral	M7-016 M7-018 M7-021 M7-023 M7-025 M7-027 M7-029 M7-031 M7-033
Carbomedics Reduced Aortic	R5-019 R5-021 R5-023 R5-025 R5-027 R5-029
Carbomedics Supra-Annular Aortic	S5-019 S5-021 S5-023 S5-025 S5-027
Carbomedics Orbis Aortic	A1-019 A1-021 A1-023 A1-025 A1-027 A1-029 A1-031
Carbomedics Orbis Mitral	M2-021 M2-023 M2-025 M2-027 M2-029 M2-031 M2-033
Carbomedics Optiform Mitral	F7-021 F7-023 F7-025 F7-027 F7-029 F7-031 F7-033

Facility(ies):

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn, 13040 Saluggia (VC), ITALY

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Product Service

EC Certificate

EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5AO 17 09 01664 016

Manufacturer:

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product: **Cardiovascular Implants**

The Certification Body of TÜV SÜD Product Service GmbH declares that a type examination has been carried out on the respective device type in accordance with the directive 93/42/EEC Annex III (4) and Regulation (EU) 722/2012 on medical devices manufactured utilizing tissues of animal origin. This representative sample of the envisaged production conforms to the requirements of the Directive and Regulation. If a certificate of the European Directorate for the Quality of Medicines (EDQM) has been issued for the respective material of animal origin, the validity of our certificate is associated with the validity of the EDQM certificate. Any changes of the EDQM certificate need to be reported immediately to TÜV SÜD Product Service GmbH by a change notification. For marketing of class III devices an additional Annex IV or V certificate is mandatory. See also notes overleaf.

Report no.: 713114103

Valid from: 2017-10-17
Valid until: 2022-07-30

Date, 2017-10-16

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5AO 17 09 01664 016

Model(s):

Carbomedics Carbo-Seal Aortovalvular Prosthesis
Carbomedics Carbo-Seal Valsalva Aortovalvular Prosthesis

Parameters:

Model Name	Product codes
Carbomedics Carbo-Seal Aortovalvular Prosthesis	AP-021 AP-023 AP-025 AP-027 AP-029 AP-031 AP-033
Carbomedics Carbo-Seal Valsalva Aortovalvular Prosthesis	CP-021 CP-023 CP-025 CP-027 CP-029

Facility(ies):

SORIN GROUP ITALIA S.r.l.
Via Crescentino sn, 13040 Saluggia (VC), ITALY

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 17 11 01664 019

Holder of Certificate: **SORIN GROUP ITALIA S.r.l.**
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Facility(ies):
SORIN GROUP ITALIA S.r.l.
Via Crescentino sn, 13040 Saluggia (VC), ITALY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:
Design and development, manufacture and distribution of medical devices intended for cardiac surgery and interventional cardiology, including implantable medical devices and their components, such as mechanical and biological heart valves, annuloplasty rings, aortovalvular prostheses, valved conduits and related accessories

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA1022444

Valid from: 2018-04-01
Valid until: 2021-03-31

Date, 2017-12-27

Stefan Preiß

Page 1 of 1

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