REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNOMEDICA"

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1002600053256

Data înregistrării **17.04.2002**

Data eliberării **16.02.2005**

Bolboceanu Adela, registrator de stat
Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT 109 L.Ș.

MD 0027040

LISTA FONDATORILOR

SRL „TEHNOMEDICA”

Fondator unic: Roibu Tatiana

IDNP: 0992606484592

Nr. de contact: +37369909500

F/COM/CC/23/02

Nr. CIF26-842.2020
Data: 13 Februarie 2020

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **Mobiasbanca - OTP Group S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **TEHNOMEDICA S.R.L.** cod fiscal (IDNO) **1002600053256**, detine următoarele conturi curente la Mobiasbanca - OTP Group S.A., Sucursala. 26 Negruzzi:

1. **MDL - MD65MO2224ASV98310887100**
2. **EUR - MD06MO2224ASV98311097100**

L.Ş.

Numele, Prenumele si Semnătura
Director sucursalei „Gheorghe Mocanu"

Executor :Eduard Cilcic
Tel: 022-812-150

Mobiasbanca - OTP Group S.A. • Capital Social: 100 000 000 MDL • Număr de înregistrare de stat – 1002600006089
bd. Ştefan cel Mare şi Sfînt 81A • MD-2012 Chişinău, Moldova • telefon: +373 22 256 456 • e-mail: info@mobiasbanca.md • www.mobiasbanca.md

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

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. № A2115026 **din** от 06.09.2021

1. Destinația / Назначение

PENTRU PARTICIPARE LA PROCEDURI DE ACHIZIȚII PUBLICE

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	**Codul fiscal / Numărul de identificare** Фискальный код / Идентификационный номер
TEHNOMEDICA S.R.L.	1002600053256

Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** Код - Наименование населенного пункта
Ciuflea nr.38 bl.1	0130-SEC.CENTRU

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

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

4. Valabil pînă la / Действителен до 21.09.2021

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

/ Șef DDF Centru — **Funcția**/Должность

V. Șestacheli — **Semnătura**/Подпись

Albina IȘCOVA — **Numele și prenumele**/Фамилия и имя

L.Ș./M.П.

Executor P. Botnari — **Numele și prenumele**/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 06.09.2021 ora 14:32:11
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)

Data prezentării 21.04.2021 14:23:33

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

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2020 - 31.12.2020

Entitatea: TEHNOMEDICA S.R.L.
Cod CUIÎO: 37700778
Cod IDNO: 1002600053256

Sediul:
MD: 2001
Raionul(municipiul): 102, DDF CENTRU
Cod CUATM: 0130, SEC.CENTRU
Strada: SECTORUL CENTRAL STR.Ciuflea nr.38 bl.1

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

Date de contact:
Telefon: +37369153407
WEB:
E-mail: ecaterin.popescu@gmail.com
Numele și coordonatele al contabilului-șef: Dl (dna) Popescu Ecaterina Tel. 022601102

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

Persoanele responsabile de semnarea situațiilor financiare* Roibu Tatiana

Unitatea de măsură: leu

BILANȚUL

Anexa 1

la

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	407	319
	din care: 2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024	407	319
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040	1404169	2861138
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	1404576	2861457
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	2364772	2174915
	din care: 3.1. clădiri	081	1147126	1038156
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	28036	34609
	3.4. mijloace de transport	084	1128114	1042950

A.	3.5. inventar și mobilier	085		
	3.6. alte mijloace fixe	086	61496	59200
	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	2364772	2174915
	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	3769348	5036372
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	31417	4996
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	1242672	1326025
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	1274089	1331021
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	1090879	1022910
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	48364	6546
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340	838	
	6. Cheltuieli anticipate curente	350	5421	13569
	7. Alte active circulante	360	63104	31297
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	1208606	1074322
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380	150000	700000
	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	150000	700000
	IV. Numerar și documente bănești	410	8666885	6916759
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	11299580	10022102
	TOTAL ACTIVE (rd.230 + rd.420)	430	15068928	15058474
	P A S I V			
C.	**CAPITAL PROPRIU** **I. Capital social și neînregistrat**			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	( )	( )
	3. Capital neînregistrat	460		
	4. Capital retras	470	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	14214199	12018454
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	2687032
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	14214199	14705486
	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	14219599	14710886
D.	**DATORII PE TERMEN LUNG**			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	din care: 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	275321	149510
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	249170	
	6. Datorii față de personal	760		977
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	324838	197101
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810		
	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	849329	347588
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	15068928	15058474

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2020 pînă la 31.12.2020

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	21436657	16620028
din care: veniturи din vînzarea produselor și mărfurilor	011	17775775	13778008
veniturи din prestarea serviciilor și executarea lucrărilor	012	3660882	2842020
veniturи din contracte de construcție	013		
veniturи din contracte de leasing	014		
veniturи din contracte de microfinanțare	015		
alte venituri din vînzări	016		
Costul vînzărilor, total	020	15063379	12527753
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	15063379	11595535
costul serviciilor prestate și lucrărilor executate terților	022		932218
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	6373278	4092275
Alte venituri din activitatea operațională	040	41518	986
Cheltuieli de distribuire	050	8704	
Cheltuieli administrative	060	2164450	1569273
Alte cheltuieli din activitatea operațională	070		17430
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	4241642	2506558

Venituri financiare, total	090	741192	1257613
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093		
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	741192	1257613
Cheltuieli financiare, total	100	680243	666851
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	680243	666851
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	60949	590762
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	60949	590762
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	4302591	3097320
Cheltuieli privind impozitul pe venit	170	569409	410288
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	3733182	2687032

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2020 pînă la 31.12.2020

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	5400			5400
	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	5400			5400
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	14214199		2195745	12018454
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	2687032		2687032
	4. Profit utilizat al perioadei de gestiune	150	X	( )	( )	( )
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	14214199	2687032	2195745	14705486
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	14219599	2687032	2195745	14710886

SITUAŢIA FLUXURILOR DE NUMERAR

de la 01.01.2020 pînă la 31.12.2020

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010	24785768	17211991
Plăți pentru stocuri și servicii procurate	020	14966422	13370873
Plăți către angajați și organe de asigurare socială și medicală	030	596384	554000
Dobînzi plătite	040		
Plata impozitului pe venit	050	408570	414542
Alte încasări	060	1459997	2220519
Alte plăți	070	4278234	5025576
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	5996155	67519
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	992852	630000
Plăți aferente rambursării creditelor și împrumuturilor	160	330000	830000
Dividende plătite	170	1968000	2019064
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	-1305148	-2219064
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	4691007	-2151545
Diferențe de curs valutar favorabile (nefavorabile)	220	-80398	401419
Sold de numerar la începutul perioadei de gestiune	230	4056276	8666885
Sold de numerar la sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	8666885	6916759

Documente atașate - Notă explicativă (fișierul pdf)

Versiune de imprimare
Salvare

Recipisa

Respondent
Codul fiscal: 1002600053256, denumire: TEHNOMEDICA S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2020
Data prezentarii: 21.04.2021
Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 21.04.2021 14:23:33

Versiune de imprimare
Salvare

Recipisa 2

Respondent
Codul fiscal: 1002600053256, denumire: TEHNOMEDICA S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2020
Data prezentarii: 21.04.2021
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 21.04.2021 18:24:30

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.

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către Centrul pentru Achiziții Publice Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1628001612167,
ID: 21042701

Declarație privind înregistrarea dispozitivelor medicale

Prin prezenta, declarăm că, produsele oferite în cadrul licitației deschise prenotate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale, precum urmează:

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declaratie de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
				97038757						
DM00002941	SET CHIRURGICA STERIL	MOLNLYCKE PROCEDURE TRAYS	RADIAL ANGIO ABSORBANT	97038757	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDIC S.R.L.	A07.PS-01.Rg04-238	22-11-2017	

I.2. Declarația de conformitate CE	Declaratie de conformitate CE
I.3. Certificatul CE	Certificat CE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
				5010783						
DM00004604	SET STERIL PENTRU ANGIOGRAFI			5010783	Germania	B. BRAUN MELSUNGEN AG	TEHNOMEDIC S.R.L.	A07.PS-01.Rg04-29	30-01-2018	

I.2. Declarația de conformitate CE	Declaratie de conformitate CE
I.3. Certificatul CE	Certificat CE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
				706100			Tehnomed			
DM00002960	CÂMP CHIRURGICA STERIL, JETABIL		ADHESIVE ABSORBENT PAD	706100	Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDIC S.R.L.	A07.PS-01.Rg04-239	27-11-2017	

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratie de conformitate CE
I.3. Certificatul CE	Certificat CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
	MĂNUȘI C						TEHNOME			
DM00002918	MĂNUȘI CHIRURGICA DIN LATEX	BIOGEL® SURGEONS	NEPUDRATE, S822 7.5 X 50, MĂRIMEA N7.5		Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDIC S.R.L.	A07.PS-01.Rg04-238	22-11-2017	
DM00002918	MĂNUȘI CHIRURGICA DIN LATEX	BIOGEL® SURGEONS	NEPUDRATE, S822 7.0 X 50, MĂRIMEA N7.0		Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDIC S.R.L.	A07.PS-01.Rg04-238	22-11-2017	
DM00002919	MĂNUȘI CHIRURGICA DIN LATEX	BIOGEL® SURGEONS	NEPUDRATE, S822 8.5 X 50, MĂRIMEA N8.5		Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDIC S.R.L.	A07.PS-01.Rg04-238	22-11-2017	
DM00002918	MĂNUȘI CHIRURGICA DIN LATEX	BIOGEL® SURGEONS	NEPUDRATE, S822 6.0 X 50, MĂRIMEA N6.0		Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDIC S.R.L.	A07.PS-01.Rg04-238	22-11-2017	
DM00002919	MĂNUȘI CHIRURGICA DIN LATEX	BIOGEL® SURGEONS	NEPUDRATE, S822 8.0 X 50, MĂRIMEA		Suedia	MÖLNLYCKE HEALTH CARE AB	TEHNOMEDIC S.R.L.	A07.PS-01.Rg04-238	22-11-2017	

Pentru restul produselor neînregistrate, declarăm că vor fi înregistrate în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale până la livrare.

Dovada înregistrării dispozitivelor medicale se regăsește pe pagina web a Agenției Medicamentului și Dispozitivelor Medicale www.amdm.gov.md

Cu respect,

Director Tatiana Roibu

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către Centrul pentru Achiziții Publice
Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1628001612167,
ID: 21042701

Declarație privind termenul de valabilitate

Prin prezenta, declarăm că termenul de valabilitate la momentul livrării a produselor oferite în cadrul licitației prenonate privind **achiziţionarea consumabilelor angiografice, conform necesităților IMSP Institutul de Cardiologie, pentru anul 2022** va constitui 80% din termenul total de valabilitate a acestora, dar nu mai mic de 12 luni.

Cu respect,

Director Tatiana Roibu

09.09.2021

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către Centrul pentru Achiziții Publice
Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1628001612167,
ID: 21042701

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante/beneficiarului pentru produsele oferite în cadrul licitației prenonate privind **achiziţionarea consumabilelor angiografice, conform necesităților IMSP Institutul de Cardiologie, pentru anul 2022.**

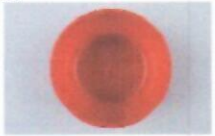
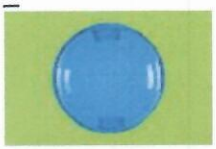
Cu respect,

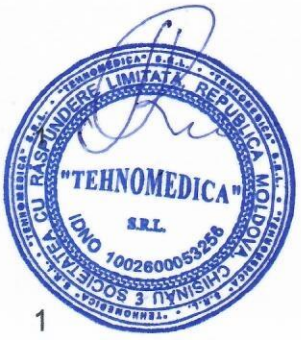
Director Tatiana Roibu

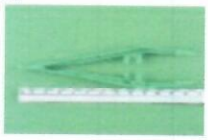
09.09.2021

Mölnlycke

Tray ID	97038757
Tray name	SET INTERVENTII RADIOGRAFICE
Colour code	
Speciality filter	ENDOVASCULAR
Intervention filter	Coronary or Peripher
Hospital filter	Tehnomedica SRL

	Description	Qty
	Crepe paper 60x60cm 60g/m2 White	1
	Angio drape 240x330cm 2 adh.ap.5x7cm 2 adh.ap.7x9cm Transp. panels	1
	Kidney bowl 800ml Yellow	1
	Adh. op towel 50x50cm	1
	Banded bag 75cm Circ. Elast. Transp.	1
	Absorbent towel 34x50cm	1
	Bowl 250ml Graduated red	1
	Bowl 2500ml Polypropylene Blue Guidewire W/tabs	1
	Specimen cup 120ml Polyethylene Transp. Blue screw-on lid	1



	Gallipot 120ml Transparent	1
	Forceps tweezer plastic green	1
	Forceps 12cm plastic green	1
	Banded bag 140cm Circ. Elast. Transp.	2
	Surg.glove latex 7.5 PF 2/1 Biogel Surgeons	2
	Surg.glove latex 8.0 PF 2/1 Biogel Surgeons	1
	Surgical gown Primary Standard Perfomance XL 127cm	1
	Hand towel 47x38cm	2
	Surgical gown Primary Standard Perfomance XL 127cm	1
	Hand towel 47x38cm	2
	Reinforced Table Cover 150 x 190 wrapping	

Article number 5010783

B|BRAUN

	Qty
Angiographic syringe 12 ml	1
Puncture Needle 1,3 x 70 mm, 18G	1
Scalpel Cutfix fig. 11	1
Guidewire J3FC-FS175-035	1
Compress gauze 10 x 10 cm, 12-ply	30
Sterican Cannula 0,80 x 40 mm, 21G	2
Sterican Cannula 0,70 x 30 mm, 22G	1
Syringe Omnifix 2 ml, Luer Lock	1
Syringe Omnifix 5 ml, Luer Lock,	1
Syringe Omnifix 10 ml, Luer Lock,	1
Syringe Omnifix 20 ml, Luer Lock,	1
Guidewire bowl 2500 ml, blue	1
Cover drape 100 x 150 cm	1
Combidyn tubing 150 cm, red	1
Rotator m/m	1
Manifold 3-fold, OFF, 35 bar	1
Tape for fixation "Japan"	2
Contrast Media System 180 cm	1
Infusionsystem ventilated 190 cm	1

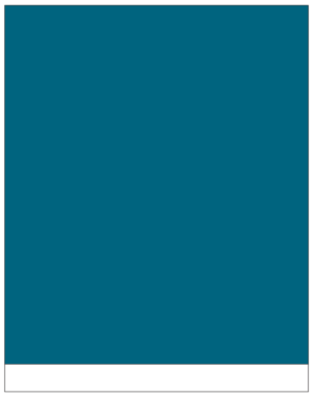
"TEHNOMEDICA" S.R.L. IDNO 1002600053256

706100
Adhesive Absorbent Pad

Product details

Size: 55cm x 70cm
Descriptive feature: Adhesive, full length
Sterility: Sterile

Images



Delivered items

706100-09

Sales released in: Australia, Austria, Azerbaijan, Bahrain, Belgium, Czechia, Denmark, Finland, Germany, Hong Kong, Hungary, Iceland, Ireland, Italy, Luxembourg, Macedonia (the former Yugoslav Republic of), Moldova (the Republic of), Netherlands, New Zealand, Norway, Portugal, Russian Federation, Slovenia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland
Country of origin: Belgium
Shelf life: 5 years
Sterilization method: Beta
Packing information: First packaging layer is a peel-open sterile barrier, plastic/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a corrugated board dispenser box. Third layer is a corrugated board transport box.

Packaging level	Pack count	GS1 code
Consumer pack	1	7323190020065
Dispenser box	40	7323190019977

Packaging level	Pack count	GS1 code
Transport box	80	7323190019960
Pallet	1920	7323190019953

Material

Animal tissues:

No

Human blood derivatives:

No

Medicinal substances:

No

Phthalates:

No

Polyvinyl chloride:

No

Product Composition Drapes

Product Component	Critical Area	Less Critical Area
Drape material	Viscose/Polyester nonwoven 80 g/m²	Viscose/Polyester nonwoven 80 g/m²
Drape material	Polyethylene film 40 µm	Polyethylene film 40 µm
Adhesive material	Synthetic rubber based	N/A

Product Performance Drapes, Additional Tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Absorption	ISO 9073-12	T-1158	g/dm²	3.66	3.66
Flammability	16 CFR 1610.4	N/A	s	Class 1, >3.5s	Class 1, >3.5s

Product Performance Sterile Drapes, EN 13795 High Performance

Characteristics	Test Method	Internal Test Method	Unit	Requirement Critical Product Area	Requirement Less Critical Product Area	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Resistance to microbial penetration - Dry	ISO 22612	T-1004	CFU	Not required	≤300	-	0
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6.0	Not required	6.0	-
Cleanliness - Particulate Matter	EN ISO 9073-10	T-1006	IPM	≤3.5	≤3.5	1.5	1.5
Linting	EN ISO 9073-10	T-1006	Log_{10} (lint count)	≤4.0	≤4.0	1.8	1.8
Resistance to liquid penetration	EN 20811	T-280	cm H_2O	≥100	≥10	>100	>100
Bursting strength - Dry	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	≥40	168	168
Bursting strength - Wet	EN ISO 13938-1	T-233 or T-1179	kPa	≥40	Not required	144	-
Tensile strength - Dry	EN 29073-3	T-229	N	≥20	≥20	36	36
Tensile strength - Wet	EN 29073-3	T-229	N	≥20	Not required	28	-

Technical

Dimension

Dimension text	Dimension value
Outer dimension	55 cm x 70 cm

Disposal instructions

Non-hazardous waste used BARRIER products and sterility barriers should, in the majority of cases, be classified as non-hazardous waste. They contain high amounts of energy and are well suited for incineration. BARRIER products do not contain any hazardous substances that can leach out if the products are land filled. Transport boxes are designed to fit existing recovery systems. The new BARRIER packaging system complies with the Packaging Waste Directive of the European Union.

Storage instructions

Mölnlycke Health Care recommends that BARRIER products are stored under normal storage conditions. All layers of packaging should be kept intact until access to the underlying layers is needed. Storage facilities for products only protected by the sterility barrier should be kept under conditions where low level of particulate air contamination prevail, so that it would not constitute a risk to the patient when the package is opened and the product is used.

Classification

Regulation type	**MDD Class IS**	**Locally Regulated**	**Unregulated**
MDD Classification Rule:	1		
CE Certificate Number:	CE 01966		
Notified body medical devices/PPE:	BSI (0086)		
Intended use MDD:	Surgical drapes, when sterilised, are intended to minimize the spread of micro-organisms, in order to reduce the risk for post operative wound infection.		
Sales released in:	Austria, Belgium, Czechia, Denmark, Finland, Germany, Hungary, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland	Australia, Azerbaijan, Bahrain, Moldova (the Republic of), New Zealand, Russian Federation, United Arab Emirates	Hong Kong, Macedonia (the former Yugoslav Republic of)

Applied standards: The standards presented below is a selection of the most essential standards that are adhered to.

EN 1041, EN 556-1, EN 13795, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1, ISO 15223-2, ISO 14001

Removable Label

Yes

GMDN Code (Global Medical Device Nomenclature)

47783

Latex
Biogel® Surgeons

The Biogel® Surgeons is a sterile, latex surgical glove with excellent barrier protection. The unique Biogel® coating provides great fit, feel and comfort and makes the glove easy to don, even with damp hands.

ACTUAL COLOUR REF 822

Biogel® key features and benefits

- 9/10 surgeons prefer Biogel for fit, feel and comfort[1]
- Reduced chance of a hole with an industry-leading AQL* result of 0.65[1]
- Every glove (100%) is air inflation tested and visually inspected for quality and safety[1]
- Improved efficiency as less gloves are wasted[2]
- Non-pyrogenic, potentially reducing the risk of post-operative complications[3]

Recommended use

Recommended for all surgical procedures.

Material information

- Natural rubber latex
- Micro-roughened surface
- Biogel hydrogel polymer coating
- Beaded cuff
- Powder-free
- Non-pyrogenic

Biogel quality

Biogel has an industry leading freedom from holes AQL* of 0.65. The industry standard requirement for AQL* is 1.5. The lower the number, the fewer the holes and the higher the quality of glove. Biogel is proven to have the lowest glove failure rate among major competitors. Non-Biogel gloves are at least 3.5 times as likely to fail than Biogel gloves[2].

Re-order REF 822

REF	Size	Pairs
82255	5½	50/Box
82260	6	50/Box
82265	6½	50/Box
82270	7	50/Box
82275	7½	50/Box
82280	8	50/Box
82285	8½	50/Box
82290	9	40/Box

4 boxes per case

MÖLNLYCKE HEALTH CARE

Product specifications Biogel® Surgeons gloves REF 822

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
82255	5.5	283	71
82260	6.0	285	77
82265	6.5	285	85
82270	7.0	288	91
82275	7.5	298	96
82280	8.0	299	103
82285	8.5	301	109
82290	9.0	301	115

Pairs per box: 50/40 for size 9

Typical thickness profile – single wall		
Cuff	8.1 mils	0.21 mm
Palm	10.0 mils	0.26 mm
Finger	10.6 mils	0.27 mm

Physical glove properties	Standard requirement	Biogel
Force at break (N) (EN455) Initial Aged	 ≥9 ≥9	 19 17
Typical accelerator analysis % w/w Dithiocarbamate (DTC)	n/a	<0.02
Diphenyl thiourea (DPTU)	n/a	none
Diphenyl guanidine (DPG)	n/a	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
Typical extractable protein (using Modified Lowry EN455/ ASTM D5712)	<50µg/g	<20µg/g
AQL* freedom from holes (1000 ml water leak test) Post packing and irradiation Process average typically	1.5	0.65 <0.20%
Grip (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)	n/a	1.0

General information

Contra-indications: This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses.

Allergenicity: Biogel gloves are produced to have low levels of aqueous extractable protein and have been shown to have a low potential for inducing allergic contact dermatitis or 'Type IV allergy'.

Pyrogenicity: Each batch of Biogel gloves is tested to have a low endotoxin level (<20 EU/pair).

Product standards: Biogel gloves are tested and manufactured to the following standards:

- **Quality/Environmental:** ISO 9001, ISO 13485, ISO 14001
- **Product:** ASTM D3577, EN455-1, EN455-2, EN455-3, EN455-4
- **Sterilisation:** Gamma irradiation
- **Viral Penetration:** Bacteriophage test, ASTM F1671
- **Allergenicity/Pyrogenicity:** ISO 10993 (PART 5 and 10)

Registering authority: In Europe the gloves are CE marked (notified body BSi, number 0086) indicating compliance with Council Directive 93/42/EEC. In US the gloves are FDA registered. Biogel Surgical gloves are a Class IIa Product.

Storage: Store in a cool, dry place away from sources of heat or direct sunlight.

Packaging: One pair per pack, in a high quality inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 50 pairs per collation case for sizes 5.5–8.5; 40 pairs for size 9.0; 200 pairs per transit case for sizes 5.5–8.5; 160 pairs for size 9.0.

Disposal: Gloves & outer wrap dispose of as clinical waste. Paper inner wrap, collation case & transit case can be recycled as paper or disposed of as clinical waste.

Shelf life: Five (5) years from date of manufacture.

Manufacturer: Made and packed in Malaysia by Mölnlycke Health Care Sdn Bhd.

Country of origin: Malaysia.

E-mail address: biogel@molnlycke.com

Date of issue: May 2012.

References: 1. Why Choose Biogel. MKT004. 2009. Data on file. 2. In Use Surgical Glove Failure Rate Comparison. Study G009-005. 2009. Data on file. 3. Biogel Endotoxin Report, Non-Pyrogenic Surgical Gloves. REPRHJV004. 2010. Data on file.

*AQL=Acceptable Quality Level refers to the maximum number of defective products that could be considered acceptable during the random sampling of an inspection, in this case freedom from holes in gloves.

Find out more at www.molnlycke.com

Mölnlycke Health Care AB, Box 13080, SE-402 52 Göteborg, Sweden.
T +46 31 722 30 00. F +46 31 722 34 00. www.molnlycke.com

MÖLNLYCKE HEALTH CARE

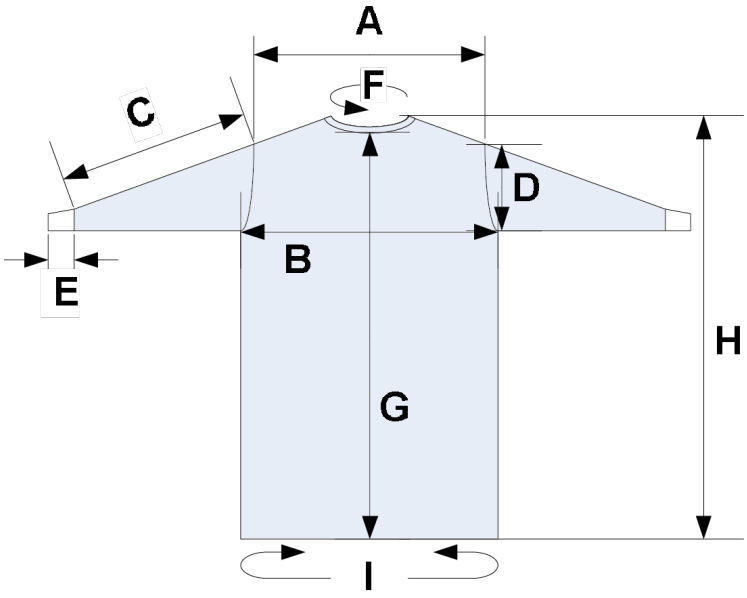
#39957

98000724
Surgical Gown PRIMARY

Product details

Size: XL
Descriptive features: Antistatic treated, High performance, Two towels, Wrapped
Color: Blue
Sterility: Sterile

Images



Delivered items

98000724-01

Country of origin: China
Shelf life: 5 years
Sterilization method: EtO

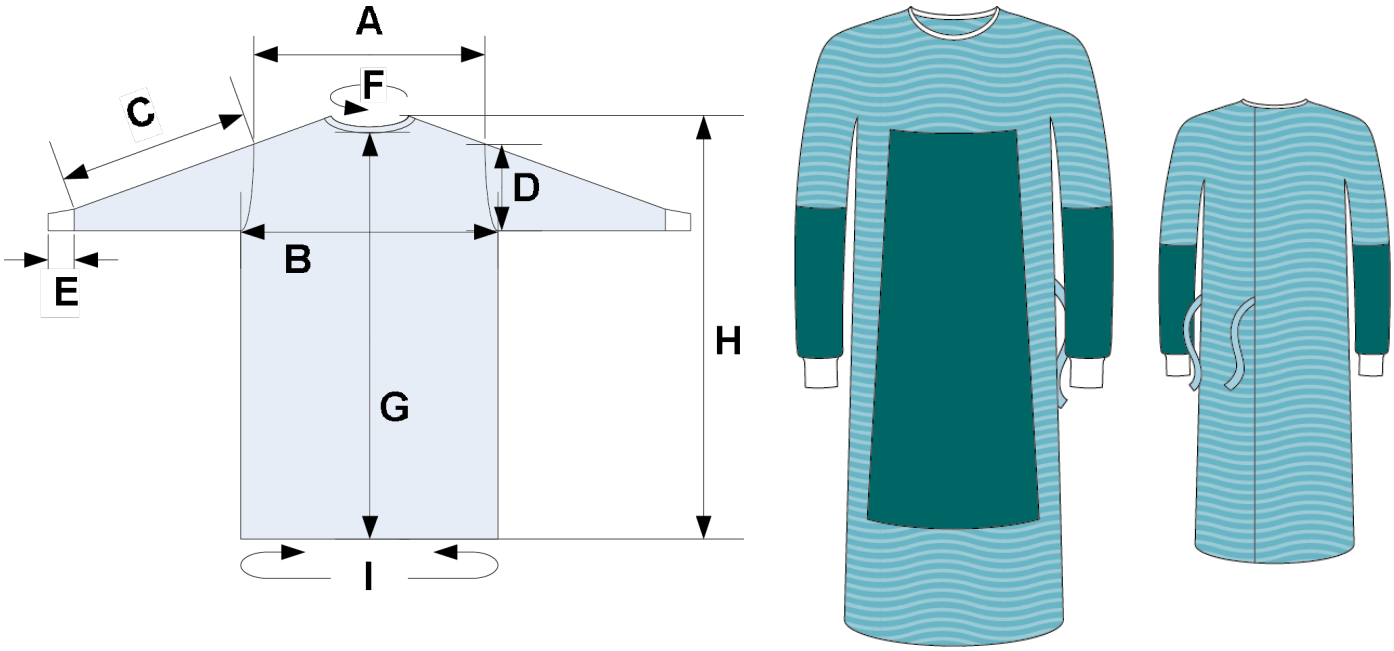
Packaging level	Pack count	GS1 code
Consumer pack	1	7332430947949
Transport box	28	7332551119478
Pallet	672	7332551119461

98000725
Surgical Gown PRIMARY

Product details

Size: XL-L
Descriptive features: Antistatic treated, High performance, Two towels, Wrapped
Color: Blue
Sterility: Sterile

Images



Delivered items

98000725-01

Country of origin: China
Shelf life: 5 years
Sterilization method: EtO

Packaging level	Pack count	GS1 code
Consumer pack	1	7332430947994
Transport box	26	7332551119508
Pallet	624	7332551119492

Material

Animal tissues:

No

Human blood derivatives:

No

Medicinal substances:

No

Phthalates:

No

Polyvinyl chloride:

No

Product Composition Surgical Gowns

Product Component	Composition
Main material	Polypropylene SMS (Spunbond Meltblown Spunbond) nonwoven 35 g/m²
Cuffs	Polyester
Outer tie-bands	Polypropylene SMS (Spunbond Meltblown Spunbond) nonwoven 35 g/m²
Inner tie-bands	Polypropylene SMS (Spunbond Meltblown Spunbond) nonwoven 35 g/m²
Neck binder	Polypropylene SMS (Spunbond Meltblown Spunbond) nonwoven 35 g/m²
Front reinforcement	Polypropylene nonwoven, Polyethylene film 33 g/m²
Sleeve reinforcement	Polypropylene nonwoven, Polyethylene film 40 g/m²

Product Performance Surgical Gowns Additional tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Spray impact	AATCC 42	N/A	g	Fabric: 0.1	Shoulder seam: 0.5
Alcohol Repellency Rating	WSP 80.8	T-283	1-10	2	2

Bursting strength - Wet	EN ISO 13938-1	T-233	kPa	≥40	Not required	125	-
Tensile strength - Dry , MD	EN 29073-3	T-229	N	≥20	≥20	87.1	87.1
Tensile strength - Dry , CD	EN 29073-3	T-229	N	≥20	≥20	Cross sleeve seam: 37	43
Tensile strength - Wet, MD	EN 29073-3	T-229	N	≥20	Not required	87	-
Tensile strength - Wet, CD	EN 29073-3	T-229	N	≥20	Not required	37	-

Product Performance Surgical Gowns AAMI level 3

Characteristics	Test Method	Internal Test Method	Unit	Requirement	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Spray impact	WSP 080.3/AATCC 42	T-1025	g	≤1	Sleeve seam: 0.02 Front w. reinf: 0.01	Shoulder seam: 0.1
Hydro head	WSP 080.6/AATCC 127	T-1030	cm H_2O	≥50	Sleeve seam:153 Reinforced front: 153	-

Technical

Dimension

Dimension text	Dimension value
Shoulder	70 cm
Chest	75 cm
Top sleeve	58 cm
Armhole	29 cm
Cuff length	6 cm

Tear, MD	WSP 100.2.R3(12)	T-1032	N	N/A	Fabric: 17
WVTR (water vapor transmission rate)	WSP 70.4.R3(12)	T-1024	g/m²/24 h	Non-breathable	63920
Air Permeability	ISO 9237	T-279	m/s	Non-breathable	N/A
Air Porosity	ASTM D737	N/A	ft³/min	Non-breathable	>72

Product Performance Surgical Gowns, EN 13795 High Performance

Characteristics	Test Method	Internal Test Method	Unit	Requirement Critical Product Area	Requirement Less Critical Product Area	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Resistance to microbial penetration - Dry	ISO 22612	T-1004	CFU	Not required	≤300	-	19
Resistance to microbial penetration - Wet	ISO 22610	T-1005	BI	6	Not required	BI 6.0	-
Cleanliness - Microbial	EN ISO 11737-1	T-303	CFU/100 cm²	≤300	≤300	<110	<110
Cleanliness - Particulate Matter	EN ISO 9073-10	T-1006	IPM	≤3.5	≤3.5	2.0	2.0
Linting	EN ISO 9073-10	T-1006	Log_{10} (lint count)	≤4.0	≤4.0	2.1	2.1
Resistance to liquid penetration	EN 20811	T-280	cm H_2O	≥100	≥10	Sleeve seam: 194. Reinforced front: 190	Shoulder seam: 16
Bursting strength - Dry	EN ISO 13938-1	T-233	kPa	≥40	≥40	194	190

Dimension text	Dimension value
Neck	72 cm
Length, highest point at shoulder	152 cm
Circumference	166 cm
Width, highest point front reinforcement	40 cm
Width, lowest point front reinforcement	63 cm
Length, front reinforcement	90 cm
Length, sleeve reinforcement	37 cm

Disposal instructions

Non-hazardous waste used BARRIER products and sterility barriers should, in the majority of cases, be classified as non-hazardous waste. They contain high amounts of energy and are well suited for incineration. BARRIER products do not contain any hazardous substances that can leach out if the products are land filled. Transport boxes are designed to fit existing recovery systems. The new BARRIER packaging system complies with the Packaging Waste Directive of the European Union.

Storage instructions

Mölnlycke Health Care recommends that BARRIER products are stored under normal storage conditions. All layers of packaging should be kept intact until access to the underlying layers is needed. Storage facilities for products only protected by the sterility barrier should be kept under conditions where low level of particulate air contamination prevail, so that it would not constitute a risk to the patient when the package is opened and the product is used.

Classification

Regulation type	MDD Class IS
MDD Classification Rule:	1
CE Certificate Number:	CE 01966
Notified body medical devices/PPE:	BSI (0086)

Regulation type	**MDD Class IS**
Intended use MDD:	The Surgical Gowns are single use, disposable, fluid repellent garments intended to be used as sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of microorganisms, body fluids and particulate material.

Applied standards: The standards presented below is a selection of the most essential standards that are adhered to.

ANSI/AAMI PB70, EN 1041, EN 556-1, EN 13795, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-7, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1, ISO 15223-2, EN ISO 10993-10, ISO 14001

Removable Label

Yes

GMDN Code (Global Medical Device Nomenclature)

35091

Reusability

Single use

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 01966**

Issued To: **Mölnlycke Health Care AB**
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

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By Royal Charter

Certificate No: CE 01966

Certificate Scope:

Those aspects of manufacture related to securing and maintaining sterility of absorbent tracheostomy dressing, sterile scar management dressing and transparent adhesive IV film dressing.

Those aspects of manufacture related to securing and maintaining sterility of negative pressure wound therapy (NPWT) accessories, surgical and equipment drapes and surgical gowns.

Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with article 12 of the MDD.

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

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Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung, dass das/die Produkt/e

hereby declare in our own responsibility that the product/s

Procedure Kits

(Artikelnummern siehe Anlage)

Procedure Kits

(article numbers see attachment)

a) die gegenseitige Kompatibilität der Geräte in Übereinstimmung mit den Anweisungen des Herstellers geprüft wird, und dass alle Operationen in Übereinstimmung mit diesen Anweisungen ausgeführt werden, und das

a) mutual compatibility of the devices in accordance with the manufacturers instructions is proven and that all operations are carried out in accordance with these instructions, and that

b) das System oder die Behandlungseinheit verpackt und sachdienliche Informationen für die Nutzer, einschließlich der einschlägigen Informationen von den Herstellern mitgeliefert werden; und

b) the system or procedure pack is packed and supplied with relevant information to users incorporating relevant information from the manufacturers; and

c) die gesamte Tätigkeit in geeigneter Weise intern überwacht und kontrolliert wird.

c) the whole activity is subjected to appropriate methods of internal control and inspection.

d) (Falls das System / Behandlungseinheit sterilisiert wird).
Die Sterilisation ist gemäß den Anweisungen des Herstellers erfolgt.

d) (If the system / procedure pack has been sterilised).
The sterilisation has been carried out in accordance with the manufacturer's instructions.

Diese Erklärung basiert auf der Grundlage

declaration is made on basis of

- Artikel 12 Absatz 2 der Medizinprodukte Richtlinie 93/42/EWG
- Paragraph 10 des Medizinproduktegesetzes (Medizinproduktegesetz, 7. August 2002)

- Article 12 part 2 of Medical Device Directive 93/42/EEC
- Paragraph 10 of Medical Devices Act (Medizinproduktegesetz, 7. August 2002)

Dieses Zertifikat ist gültig für die im Anhang I genannten Procedure Kits hergestellt von der B. Braun Melsungen AG, 34209 Melsungen, Deutschland

This certificate is valid for the procedure kits mentioned in the Attachment I manufactured by B. Braun Melsungen AG, 34209 Melsungen, Germany

Datum der ersten Erklärung
2015-01

Date of first declaration
2015-01

Gültig bis
2024-05-26

Valid until
2024-05-26

Berlin, 2020-05-19

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein
Head of Quality Management CoE VS

Berlin, 2020-05-19

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht
Head of Regulatory Affairs

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Enthält Komponenten der Klasse/ contains components of Class
5010687	Hahnbankset Uni Münster	Hahnbankset Uni Münster	IIa
5010690	Feinnadelset KH-Stuttgart	Feinnadelset KH-Stuttgart	IIa
5010691	Angiodyn Coroset Villingen-Schwenningen	Angiodyn Coroset Villingen-Schwenningen	IIa
5010701	Coroset Nagold	Coroset Nagold	IIa
5010709	PTCA Set	PTCA Set	IIa
5010714	Port-Punktionsset	Port-Punktionsset	IIa
5010720	EP-Set	EP-Set	IIa
5010727	Laser-Set, KSSP Aarau	Laser-Set, KSSP Aarau	IIa
5010744	Toimenpidesetti Seinäjoe ks, röntgen	Toimenpidesetti Seinäjoe ks, röntgen	IIa
5010764	Angiodynset 3FRR35 15360	Angiodynset 3FRR35 15360	IIa
5010778	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	IIa
5010782	Pädiatrie-Set Uni Homburg	Pädiatrie-Set Uni Homburg	IIa
5010783	Set steril pentru Angiografie	Set steril pentru Angiografie	IIa
5010786	Hybrid Set Hirslanden Zürich	Hybrid Set Hirslanden Zürich	IIa
5010794	Angiosetti PHKS, ELFYS	Angiosetti PHKS, ELFYS	IIa
5010800	Bowl 90ml, Round, Blue	Bowl 90ml, Round, Blue	I
5010801	Tab. Neuro / Angiograpfia – H. Egas Moniz	Tab. Neuro / Angiograpfia – H. Egas Moniz	IIa
5010804	Epiduraalsetti Vaasan ks	Epiduraalsetti Vaasan ks	IIa
5010805	EPU Set HZ Dresden	EPU Set HZ Dresden	IIa
5010806	Hahnbankset Nagold	Hahnbankset Nagold	IIb
5010808	Contrast-Saver HKZ Rotenburg	Contrast-Saver HKZ Rotenburg	IIa
5010811	NNI – Angiography Set	NNI – Angiography Set	IIa
5010817	UNI-Set_Novomed	UNI-Set_Novomed	IIa
5010820	Angiodyn-Schale, 60 ml, transp.	Angiodyn-Bowl, 60 ml, transp.	Is
5010830	Cover Drape 90 X 90 CM	Cover Drape 90 X 90 CM	I
5010833	Sahlgrenska Sotra	Sahlgrenska Sotra	IIa
5010840	Kidney Dish Blue	Kidney Dish Blue	I
5010850	Cover Drape 152 X 228 CM	Cover Drape 152 X 228 CM	I
5010860	Angiodyn-Schale, 120 ml, transp.	Angiodyn-Bowl, 120 ml, transp.	Is
5010868	PTCA Set Bad Rothenfelde	PTCA Set Bad Rothenfelde	IIa
5010871	Angiodyn HKL-Set Bad Tölz	Angiodyn HKL-Set Bad Tölz	IIa
5010874	Untersuchungskittel, Gr. XL	Untersuchungskittel, Gr. XL	Is
5010878	Skejby højre side pakke	Skejby højre side pakke	IIa
5010880	Paineemittaussetti malli 2	Paineemittaussetti malli 2	IIb

Title: Mölnlycke Procedure Trays MDD Article 12 (former Class IIa trays)

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the assembler of the following declare that the procedure packs listed in the attached schedule are in conformity with the provisions of Article 12 in the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade Name: *Mölnlycke® Procedure Trays*

The mutual compatibility of each device within the Mölnlycke Health Care procedure packs has been verified in accordance with the relevant instructions for use provided by the manufacturer of each device and / or the approved indications for use of each device.

Where appropriate, the relevant instructions for use are provided.

Procedure packs are assembled in accordance with a documented quality management system and therefore, subject to internal controls and inspection prior to release that ensures the safety, quality and performance of the procedure pack.

Sterilisation after assembly:	*EtO, Ethylene Oxide*
CE certificate	*CE 01966*
Certificate issued by	*BSi (0086)*

For sterilised procedure packs, the sterilisation process is performed in accordance with the manufacturer(s)' instructions and follows the procedures of Annex V of 93/42/EEC.

For systems and procedure packs, the intervention of the notified body is limited to the aspects of the procedure relating to the obtaining of sterility.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:

Name of signing person
RA Manager, Medical Devices

Product reference	Product Name	Product Description / included devices	GMDN code
See products linked to this document in the ERP system.			

Product name, article number, manufacturer and notified body number for each device included in the system or procedure pack can be found in the BOM in the ERP system.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:

Name of signing person

RA Manager, Medical Devices

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

Holds Certificate Number: **MD 83345**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves.
The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-07-21
Effective Date: 2018-11-28
Latest Revision Date: 2018-11-26
Expiry Date: 2021-11-27

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Certificate No: **MD 83345**

Location	Registered Activities
Mölnlycke Health Care AB Box 13080 Gamlestadsvägen 3C SE-402 52 Göteborg Sweden	The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves. The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.
Molnlycke Health Care Pty Ltd Level 4 12 Narabang Way Belrose New South Wales 2085 Australia	The provision of sales, marketing, and distribution of sterile wound and scar dressings, open wound products, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and supports, sterile irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves and laparoscopic instruments.

Original Registration Date: 2004-07-21

Effective Date: 2018-11-28

Latest Revision Date: 2018-11-26

Expiry Date: 2021-11-27

MÖLNLYCKE HEALTH CARE

Document ID: BI1008lat - 3

EC Declaration of Conformity

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, SE-402 52 Göteborg, Box 13080, SE-402 52 Göteborg, Sweden being the manufacturer of the following, declare that the devices listed in the attached schedule is in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993,as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by 2009:18.

Trade name/ Product name:	Biogel Sterile latex Powder Free surgical gloves

Product classification	IIa	(choice: Class I, Class IIa, Class IIb, Class III)
Sterility	S	(choice: sterile, non sterile)
Measuring function	no	(choice: yes, no)

This declaration is supported by a conformity assessment procedure in accordance with Annex/es V + VII

Certificate number: CE 91450

Issued by BSi

For non sterile, non-measuring class I products, no certificate is issued by a Notified Body.

MHC issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

Date: April 21, 2010 Function: EMEA Director Regulatory Affairs

Name: Kathleen Harris Signature: Kathleen Harris

Schedule:

Ref.	LATEX - Single Gloving
S822	BIOGEL SURGEONS
S304	BIOGEL SURGEONS
S961	BIOGEL SURGEONS
S305	BIOGEL M SURGEONS
S962	BIOGEL M SURGEONS
S823	BIOGEL M SURGEONS
S825	BIOGEL SUPER SENSITIVE
S975	BIOGEL SUPER SENSITIVE
S306	BIOGEL SENSOR
S310	BIOGEL OPTIFIT ORTHOPAEDIC
S826	BIOGEL OPTIFIT S/SENSITIVE
S321	Biogel OrthoPro
S326	Biogel OrthoPro Underglove
S329	Biogel OrthoPro Indicator Overglove
	LATEX - Double Gloving
S842	BIOGEL INDICATOR
S312	BIOGEL INDICATOR U/GLOVES
S942	BIOGEL INDICATOR U/GLOVES
S941	BIOGEL REVEAL

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2000

This is to certify that:

Mölnlycke Health Care AB
Gamlestadvägen 3 C
S-402 52
Göteborg
Sweden

Holds Certificate No: **FM 39247**

and operates a Quality Management System which complies with the requirements of ISO 9001:2000 for the following scope:

The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves.

The design, development and manufacture of pharmaceuticals and other healthcare products.

For and on behalf of BSI:

Managing Director, BSI Management Systems (CEMEA)

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

UKAS QUALITY MANAGEMENT 003

Certificate No: **FM 39247**

Location	***Registered Activities***
Mölnlycke Health Care AB Gamlestadsvägen 3 C S-402 52 Göteborg Sweden	The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves. The design, development and manufacture of pharmaceuticals and other healthcare products.
Mölnlycke Health Care Oy PO Box 76 Saimaankatu 6 Mikkeli FIN 50101 Finland	Manufacture of swabs, sponges, towels, wound dressings, open wound products, scar dressings and procedure packs.
Mölnlycke Health Care AB Mölnlycke Health Care (Thailand) Lt 160 Bangplee Industrial Estate Bangna-Trad Rd Samutprakarn Bansaothong 10540 Thailand	Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.
Mölnlycke Health Care AB T/A Mölnlycke Health Care SA Parc Industrial B-4300 Waremme Belgium	Manufacture of sterile drapes, operating sets and procedure packs.
Mölnlycke Health Care Klinipro s.r. Na Novem Poli 382 Prumyslova zona Karvina Karvina - State Mesto 733 01 Czech Republic	Manufacture of surgical drapes and procedure packs.

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

Certificate No: **FM 39247**

Location	***Registered Activities***
Mölnlycke Health Care AB Mölnlycke Health Care (Thailand) Lt Amata Nakorn (Bang Pakong) Industrial Estate 700/461 Moo Bangha-Trad Rd. KM.57 Tambol Donhuaroh, Amphur Muang Chonburi 20000 Thailand	Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.
Mölnlycke Health Care AB Tubiton House Medlock Street Oldham OL1 3HS United Kingdom	The design, development and manufacture of sterile wound dressings, non sterile textile bandages and supports, procedure packs, sterile irrigation solutions, sterile alcohol wipes, skin care products, pharmaceuticals and other healthcare products.
Mölnlycke Health Care AB Lot 9, Lorong Perusahaan 4 Kulim Industrial Estate PO Box 52, 09000 Kulim Kedah Darulaman Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.
Mölnlycke Health Care AB Plot 204 Kawasan Perindustrian Kula Ketil Phas II 09300 Kula Ketil Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.
Mölnlycke Health Care AB Lot B5 & B6 Kawasan Perindustrian Miel Batang Kali Phase II 44300 Batang Kali Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**