

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*

**MD 0027040**



# **LISTA FONDATORILOR**

**SRL „TEHNOMEDICA”**

***Fondator unic: Roibu Tatiana***

***IDNP: 0992606484592***

***Nr. de contact: +37369909500***

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.S.  
Numele, Prenumele si Semnatura  
Director sucursalei „Gheorghe Mocanu”



Executor :Eduard Cilcic  
Tel: 022-812-150

**CERTIFICAT**  
**privind lipsa sau existența restanțelor față de bugetul public național**

Nr.  
№ A2115824

din  
от 20.09.2021

**1. Destinația / Назначение**

PENTRU PARTICIPARE LA PROCEDURI DE ACHIZIȚII PUBLICE

**2. Date despre contribuabil / Информация о налогоплательщике**

|                                                                                               |                                                                                    |
|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| Denumirea<br>Наименование                                                                     | Codul fiscal / Numărul de identificare<br>Фискальный код / Идентификационный номер |
| TEHNOMEDICA S.R.L.                                                                            | 1002600053256                                                                      |
| Adresa sediului de bază (strada, numărul)<br>Адрес основного месторасположения (улица, номер) | Codul - Denumirea localității<br>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 05.10.2021**

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



Semnătura/Подпись

Albina IȘCOVA  
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 20.09.2021 ora 14:02:46  
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)

SITUAȚIILE FINANCIARE  
pentru perioada 01.01.2020 - 31.12.2020

Entitatea: TEHNOMEDICA S.R.L.  
Cod CUIO: 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: DI (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

| Nr. cpt. | Indicatori                                                           | Cod rd. | Sold la                         |                                 |
|----------|----------------------------------------------------------------------|---------|---------------------------------|---------------------------------|
|          |                                                                      |         | Începutul perioadei de gestiune | Sfârșitul 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:                                                            | 021     |                                 |                                 |
|          | 2.1. concesiuni, licențe și mărci                                    |         |                                 |                                 |
|          | 2.2. drepturi de autor și titluri de protecție                       | 022     |                                 |                                 |
|          | 2.3. programe informatice                                            | 023     |                                 |                                 |
|          | 2.4. alte imobilizări necorporale                                    | 024     | 407                             | 319                             |
|          | 3. Fond comercial                                                    | 030     |                                 |                                 |
|          | 4. Avansuri acordate pentru imobilizări necorporale                  | 040     | 1404169                         | 2861138                         |
|          | Total imobilizări necorporale<br>(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:                                                            | 081     | 1147126                         | 1038156                         |
|          | 3.1. clădiri                                                         |         |                                 |                                 |
|          | 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 |         |         |
|    | <b>Total imobilizări corporale</b><br>(rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)                     | 130 | 2364772 | 2174915 |
|    | <b>III. Investiții financiare pe termen lung</b>                                                                         |     |         |         |
|    | 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 |         |         |
|    | <b>Total investiții financiare pe termen lung</b><br>(rd.140 + rd.150)                                                   | 160 |         |         |
|    | <b>IV. Creanțe pe termen lung și alte active imobilizate</b>                                                             |     |         |         |
|    | 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 |         |         |
|    | <b>Total creanțe pe termen lung și alte active imobilizate</b><br>(rd.170 + rd.180 + rd.190 + rd.200 + rd.210)           | 220 |         |         |
|    | <b>TOTAL ACTIVE IMOBILIZATE</b><br>(rd.050 + rd.130 + rd.160 + rd.220)                                                   | 230 | 3769348 | 5036372 |
| B. | <b>ACTIVE CIRCULANTE</b>                                                                                                 |     |         |         |
|    | <b>I. Stocuri</b>                                                                                                        |     |         |         |
|    | 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 |         |         |
|    | <b>Total stocuri</b><br>(rd.240 + rd.250 + rd.260 + rd.270 + rd.280)                                                     | 290 | 1274089 | 1331021 |
|    | <b>II. Creanțe curente și alte active circulante</b>                                                                     |     |         |         |
|    | 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   |
|    | <b>Total creanțe curente și alte active circulante</b><br>(rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360) | 370 | 1208606 | 1074322 |
|    | <b>III. Investiții financiare curente</b>                                                                                |     |         |         |
|    | 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 |          |          |
|    | <b>Total investiții financiare curente</b><br>(rd.380 + rd.390)                                       | 400 | 150000   | 700000   |
|    | <b>IV. Numerar și documente bănești</b>                                                               | 410 | 8666885  | 6916759  |
|    | <b>TOTAL ACTIVE CIRCULANTE</b><br>(rd.290 + rd.370 + rd.400 + rd.410)                                 | 420 | 11299580 | 10022102 |
|    | <b>TOTAL ACTIVE</b><br>(rd.230 + rd.420)                                                              | 430 | 15068928 | 15058474 |
|    | <b>P A S I V</b>                                                                                      |     |          |          |
| C. | <b>CAPITAL PROPRIU</b>                                                                                |     |          |          |
|    | <b>I. Capital social și neînregistrat</b>                                                             |     |          |          |
|    | 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 |          |          |
|    | <b>Total capital social și neînregistrat</b><br>(rd.440 + rd.450 + rd.460 + rd.470 + rd.480)          | 490 | 5400     | 5400     |
|    | <b>II. Prime de capital</b>                                                                           | 500 |          |          |
|    | <b>III. Rezerve</b>                                                                                   |     |          |          |
|    | 1. Capital de rezervă                                                                                 | 510 |          |          |
|    | 2. Rezerve statutare                                                                                  | 520 |          |          |
|    | 3. Alte rezerve                                                                                       | 530 |          |          |
|    | <b>Total rezerve</b><br>(rd.510 + rd.520 + rd.530)                                                    | 540 |          |          |
|    | <b>IV. Profit (pierdere)</b>                                                                          |     |          |          |
|    | 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        | ( )      |
|    | <b>Total profit (pierdere)</b><br>(rd.550 + rd.560 + rd.570 + rd.580)                                 | 590 | 14214199 | 14705486 |
|    | <b>V. Rezerve din reevaluare</b>                                                                      | 600 |          |          |
|    | <b>VI. Alte elemente de capital propriu</b>                                                           | 610 |          |          |
|    | <b>TOTAL CAPITAL PROPRIU</b><br>(rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)                 | 620 | 14219599 | 14710886 |
| D. | <b>DATORII PE TERMEN LUNG</b>                                                                         |     |          |          |
|    | 1. Credite bancare pe termen lung                                                                     | 630 |          |          |
|    | 2. Împrumuturi pe termen lung                                                                         | 640 |          |          |
|    | din care:                                                                                             | 641 |          |          |
|    | 2.1. împrumuturi din emisiunea de obligațiuni                                                         |     |          |          |
|    | inclusiv: împrumuturi din emisiunea de obligațiuni convertibile                                       | 642 |          |          |
|    | 2.2. alte împrumuturi pe termen lung                                                                  | 643 |          |          |
|    | 3. Datorii comerciale pe termen lung                                                                  | 650 |          |          |
|    | 4. Datorii față de părțile afiliate pe termen lung                                                    | 660 |          |          |
|    | inclusiv: datorii aferente intereselor de participare                                                 | 661 |          |          |
|    | 5. Avansuri primite pe termen lung                                                                    | 670 |          |          |
|    | 6. Venituri anticipate pe termen lung                                                                 | 680 |          |          |
|    | 7. Alte datorii pe termen lung                                                                        | 690 |          |          |
|    | <b>TOTAL DATORII PE TERMEN LUNG</b><br>(rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690) | 700 |          |          |
|    | <b>DATORII CURENTE</b>                                                                                |     |          |          |
|    | 1. Credite bancare pe termen scurt                                                                    | 710 |          |          |
|    | 2. Împrumuturi pe termen scurt, total                                                                 | 720 |          |          |

|    |                                                                                                                                    |     |          |          |
|----|------------------------------------------------------------------------------------------------------------------------------------|-----|----------|----------|
| E. | din care:                                                                                                                          | 721 |          |          |
|    | 2.1. împrumuturi din emisiunea de obligațiuni                                                                                      |     |          |          |
|    | inclusiv: împrumuturi din emisiunea de obligațiuni convertibile                                                                    | 722 |          |          |
|    | 2.2. alte împrumuturi pe termen scurt                                                                                              | 723 |          |          |
|    | 3. Datorii comerciale curente                                                                                                      | 730 | 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 |          |          |
|    | <b>TOTAL DATORII CURENTE</b><br>(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. | <b>PROVIZIOANE</b>                                                                                                                 |     |          |          |
|    | 1. Provizioane pentru beneficiile angajaților                                                                                      | 830 |          |          |
|    | 2. Provizioane pentru garanții acordate cumpărătorilor/clientilor                                                                  | 840 |          |          |
|    | 3. Provizioane pentru impozite                                                                                                     | 850 |          |          |
|    | 4. Alte provizioane                                                                                                                | 860 |          |          |
|    | <b>TOTAL PROVIZIOANE</b><br>(rd.830 + rd.840 + rd.850 + rd.860)                                                                    | 870 |          |          |
|    | <b>TOTAL PASIVE</b><br>(rd.620 + rd.700 + rd.820 + rd.870)                                                                         | 880 | 15068928 | 15058474 |

SITUAȚIA DE PROFIT ȘI PIERDERE  
de la 01.01.2020 până la 31.12.2020

Anexa 2

| Indicatori                                                                                                        | Cod rd. | Perioada de gestiune |          |
|-------------------------------------------------------------------------------------------------------------------|---------|----------------------|----------|
|                                                                                                                   |         | precedenta           | curenta  |
| 1                                                                                                                 | 2       | 3                    | 4        |
| Venituri din vânzări, total                                                                                       | 010     | 21436657             | 16620028 |
| din care:                                                                                                         |         |                      |          |
| venituri din vânzarea produselor și mărfurilor                                                                    | 011     | 17775775             | 13778008 |
| venituri din prestarea serviciilor și executarea lucrărilor                                                       | 012     | 3660882              | 2842020  |
| venituri din contracte de construcție                                                                             | 013     |                      |          |
| venituri din contracte de leasing                                                                                 | 014     |                      |          |
| venituri din contracte de microfinanțare                                                                          | 015     |                      |          |
| alte venituri din vânzări                                                                                         | 016     |                      |          |
| Costul vânzărilor, total                                                                                          | 020     | 15063379             | 12527753 |
| din care:                                                                                                         |         |                      |          |
| valoarea contabilă a produselor și mărfurilor vândute                                                             | 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 vânzărilor                                                                                  | 026     |                      |          |
| <b>Profit brut (pierdere brută)</b> (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    |
| <b>Rezultatul din activitatea operațională: profit (pierdere)</b><br>(rd.030 + rd.040 - rd.050 - rd.060 - rd.070) | 080     | 4241642              | 2506558  |

|                                                                                                             |     |         |         |
|-------------------------------------------------------------------------------------------------------------|-----|---------|---------|
| Venituri financiare, total                                                                                  | 090 | 741192  | 1257613 |
| din care:                                                                                                   | 091 |         |         |
| venituri din interese de participare                                                                        |     |         |         |
| inclusiv: veniturile obținute de la părțile afiliate                                                        | 092 |         |         |
| venituri din dobânzi                                                                                        | 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:                                                                                                   | 101 |         |         |
| cheltuieli privind dobânzile                                                                                |     |         |         |
| 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  |
| <b>Rezultatul: profit (pierdere) financiar(ă)</b> (rd.090 - rd.100)                                         | 110 | 60949   | 590762  |
| Venituri cu active imobilizate și excepționale                                                              | 120 |         |         |
| Cheltuieli cu active imobilizate și excepționale                                                            | 130 |         |         |
| <b>Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere)</b> (rd.120 - rd.130) | 140 |         |         |
| <b>Rezultatul din alte activități: profit (pierdere)</b> (rd.110 + rd.140)                                  | 150 | 60949   | 590762  |
| <b>Profit (pierdere) pînă la impozitare</b> (rd.080 + rd.150)                                               | 160 | 4302591 | 3097320 |
| Cheltuieli privind impozitul pe venit                                                                       | 170 | 569409  | 410288  |
| <b>Profit net (pierdere netă) al perioadei de gestiune</b> (rd.160 - rd.170)                                | 180 | 3733182 | 2687032 |

SITUAȚIA 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.      | <b>Capital social și neînregistrat</b>                                                    |        |                                         |          |           |                                         |
|         | 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    |                                         |          |           |                                         |
|         | <b>Total capital social și neînregistrat</b> (rd.010 + rd.020 + rd.030 + rd.040 + rd.050) | 060    | 5400                                    |          |           | 5400                                    |
| II.     | <b>Prime de capital</b>                                                                   | 070    |                                         |          |           |                                         |
| III.    | <b>Rezerve</b>                                                                            |        |                                         |          |           |                                         |
|         | 1. Capital de rezervă                                                                     | 080    |                                         |          |           |                                         |
|         | 2. Rezerve statutare                                                                      | 090    |                                         |          |           |                                         |
|         | 3. Alte rezerve                                                                           | 100    |                                         |          |           |                                         |
|         | <b>Total rezerve</b> (rd.080 + rd.090 + rd.100)                                           | 110    |                                         |          |           |                                         |
|         | <b>Profit (pierdere)</b>                                                                  |        |                                         |          |           |                                         |
|         | 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        | ( )     | ( )     | ( )      |
|     | <b>Total profit (pierdere)</b><br>(rd.120 + rd.130 + rd.140 + rd.150)                 | 160 | 14214199 | 2687032 | 2195745 | 14705486 |
| V.  | <b>Rezerve din reevaluare</b>                                                         | 170 |          |         |         |          |
| VI. | <b>Alte elemente de capital propriu</b>                                               | 180 |          |         |         |          |
|     | <b>Total capital propriu</b><br>(rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180) | 190 | 14219599 | 2687032 | 2195745 | 14710886 |

SITUAȚIA FLUXURILOR DE NUMERAR  
de la 01.01.2020 până la 31.12.2020

Anexa 4

| Indicatori                                                                                                                  | Cod rd | Perioada de gestiune |          |
|-----------------------------------------------------------------------------------------------------------------------------|--------|----------------------|----------|
|                                                                                                                             |        | precedentă           | curentă  |
| 1                                                                                                                           | 2      | 3                    | 4        |
| <b>Fluxuri de numerar din activitatea operațională</b>                                                                      |        |                      |          |
| Încasări din vânzări                                                                                                        | 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   |
| Dobânzi plătite                                                                                                             | 040    |                      |          |
| Plata impozitului pe venit                                                                                                  | 050    | 408570               | 414542   |
| Alte încasări                                                                                                               | 060    | 1459997              | 2220519  |
| Alte plăți                                                                                                                  | 070    | 4278234              | 5025576  |
| <b>Fluxul net de numerar din activitatea operațională</b><br>(rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070) | 080    | 5996155              | 67519    |
| <b>Fluxuri de numerar din activitatea de investiții</b>                                                                     |        |                      |          |
| Încasări din vânzarea activelor imobilizate                                                                                 | 090    |                      |          |
| Plăți aferente intrărilor de active imobilizate                                                                             | 100    |                      |          |
| Dobânzi încasate                                                                                                            | 110    |                      |          |
| Dividende încasate                                                                                                          | 120    |                      |          |
| inclusiv: dividende încasate din străinătate                                                                                | 121    |                      |          |
| Alte încasări (plăți)                                                                                                       | 130    |                      |          |
| <b>Fluxul net de numerar din activitatea de investiții</b><br>(rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)                  | 140    |                      |          |
| <b>Fluxuri de numerar din activitatea financiară</b>                                                                        |        |                      |          |
| 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    |                      |          |
| <b>Fluxul net de numerar din activitatea financiară</b><br>(rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)                     | 200    | -1305148             | -2219064 |
| <b>Fluxul net de numerar total</b><br>(± rd.080 ± rd.140 ± rd.200)                                                          | 210    | 4691007              | -2151545 |
| Diferențe de curs valutar favorabile (nefavorabile)                                                                         | 220    | -80398               | 401419   |
| <b>Sold de numerar la începutul perioadei de gestiune</b>                                                                   | 230    | 4056276              | 8666885  |
| <b>Sold de numerar la sfârșitul perioadei de gestiune</b><br>(± rd.210 ± rd.220 + rd.230)                                   | 240    | 8666885              | 6916759  |

[Versiune de imprimare](#)

[Salvare](#)

## Recipisa

Respondent

Codul fiscal: 1002600053256, denumire: TEHNOMEDICA S.R.L.

A prezentat raportul: RSF1\_21

Pentru perioada fiscală: A/2020

Data prezentării: 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](mailto:tehnomedica_md@yahoo.com)> <[tehnomedicamd@gmail.com](mailto:tehnomedicamd@gmail.com)>

**Către Centrul pentru Achiziții Publice  
Centralizate în Sănătate**

În atenția Grupului de lucru  
al Licităției deschise **nr. ocds-b3wdp1-MD-1629357933484,**  
**ID: 21043459**

## **Declarație privind disponibilitatea prezentării mostrelor**

Prin prezenta, declarăm că vom prezenta mostre la solicitarea autorității contractante pentru produsele oferite în cadrul licitației prenotate privind **achiziționarea dispozitivelor medicale (pansamente) conform Programului Național pentru combaterea maladiilor rare - "Epidermoliza buloasă", pentru anul 2022.**

Totodată, menționăm că pansamentele oferite sunt bine cunoscute și utilizate în tratamentul pacienților care suferă de epidermoliza buloasă și au demonstrat eficiența în minimalizarea complicațiilor specifice patologiei. Studii clinice și informații extrase din ghidurile internaționale privind tratamentul simptomatic cu utilizarea pansamentelor atraumatice sunt anexate la ofertă. La solicitare, pot fi furnizate mai multe studii clinice relevante, ce nu pot fi plasate pe platforma electronică a achizițiilor, dat fiind volumul considerabil al fișierelor.

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](mailto:tehnomedica_md@yahoo.com)> <[tehnomedicamd@gmail.com](mailto:tehnomedicamd@gmail.com)>

**Către Centrul pentru Achiziții Publice  
Centralizate în Sănătate**

În atenția Grupului de lucru  
al Licităției deschise **nr. ocds-b3wdp1-MD-1629357933484,**  
**ID: 21043459**

## **Declarație privind termenul de valabilitate**

Prin prezenta, declarăm că termenul de valabilitate a produselor oferite în cadrul licitației prenotate privind **achiziționarea dispozitivelor medicale (pansamente) conform Programului Național pentru combaterea maladiilor rare - "Epidermoliza buloasă", pentru anul 2022** va constitui cel puțin 80% din termenul total de valabilitate a acestora la momentul livrării, dar nu mai mic de 12 luni.

Cu respect,

Director

Tatiana Roibu

# TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chişinău, 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 Licităției deschise nr. ocds-b3wdp1-MD-1629357933484,  
ID: 21043459

### 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                           |
|--------------------------------------------------------------------|------------------------------------|
| II.3. Instrucțiunile de utilizare                                  | Instrucțiuni de utilizare_Original |
| II.3. Instrucțiunile de utilizare                                  | Sticker                            |
| I.3. Certificatul CE                                               | Certificat CE                      |
| II.2. Eticheta (etichete) dispozitivului medical și al ambalajului | Eticheta secundara_20 x 50 cm      |
| II.2. Eticheta (etichete) dispozitivului medical și al ambalajului | Eticheta primara_20 x 50 cm        |
| II.2. Eticheta (etichete) dispozitivului medical și al ambalajului | Eticheta secundara_15 x 20 cm      |
| II.2. Eticheta (etichete) dispozitivului medical și al ambalajului | Eticheta primara_15 x 20 cm        |
| II.2. Eticheta (etichete) dispozitivului medical și al ambalajului | Sticker                            |
| I.2. Declarația de conformitate CE                                 | Declarație de conformitate CE      |

| Введите текст для поиска...          |                                                        |                                |            |             |        |                          |                    |                   |            |
|--------------------------------------|--------------------------------------------------------|--------------------------------|------------|-------------|--------|--------------------------|--------------------|-------------------|------------|
| Nr                                   | Denumire                                               | Den.comerc.                    | Model      | Nr. catalog | Tara   | Producatorul             | Reprezentant       | Ordin             | Data       |
| DM000021619                          | PANSAMENT CU SILICON MOALE PENTRU TRANSFERUL EXUDATIEI | MEPILEX®TRAN WITH SAFETAC®TECH | 20 X 50 CM | 294502      | Suedia | MÖLNLYCKE HEALTH CARE AB | TEHNOMEDICA S.R.L. | A07.PS-01.Rg04-83 | 28-04-2017 |
| ✓ Conexiuni([Nr. catalog], "294502") |                                                        |                                |            |             |        |                          |                    |                   |            |



AGENȚIA MEDICAMENTULUI  
ȘI DISPOZITIVELOR MEDICALE

#### REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

| Tip                                                                | Denumire                           |
|--------------------------------------------------------------------|------------------------------------|
| I.2. Declarația de conformitate CE                                 | Declarație de conformitate CE      |
| I.3. Certificatul CE                                               | Certificat CE                      |
| II.3. Instrucțiunile de utilizare                                  | Sticker                            |
| II.3. Instrucțiunile de utilizare                                  | Instrucțiuni de utilizare_Original |
| II.2. Eticheta (etichete) dispozitivului medical și al ambalajului | Eticheta_primara                   |
| II.2. Eticheta (etichete) dispozitivului medical și al ambalajului | Sticker                            |
| II.2. Eticheta (etichete) dispozitivului medical și al ambalajului | Eticheta_secundara                 |

| Введите текст для поиска...          |                                                                          |                                      |                |             |        |                          |                    |                   |            |
|--------------------------------------|--------------------------------------------------------------------------|--------------------------------------|----------------|-------------|--------|--------------------------|--------------------|-------------------|------------|
| Nr                                   | Denumire                                                                 | Den.comerc.                          | Model          | Nr. catalog | Tara   | Producatorul             | Reprezentant       | Ordin             | Data       |
| DM000021554                          | PANSAMENT DIN SPUMA POLIURETANICA CU STRAT NON-ADERENT DIN SILICON MOALE | MEPILEX® EM WITH SAFETAC® TECHNOLOGY | 17.5 X 17.5 CM | 284322      | Suedia | MÖLNLYCKE HEALTH CARE AB | TEHNOMEDICA S.R.L. | A07.PS-01.Rg04-83 | 28-04-2017 |
| ✓ Conexiuni([Nr. catalog], "284322") |                                                                          |                                      |                |             |        |                          |                    |                   |            |

Dovada înregistrării dispozitivelor medicale se regăsește pe pagina web a Agenției Medicamentului și Dispozitivelor Medicale [www.amdm.gov.md](http://www.amdm.gov.md)

Cu respect,

Director

Tatiana Roibu

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.****CE 01965****Issued To:**

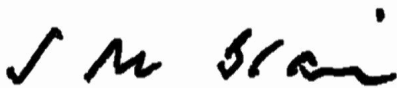
**Mölnlycke Health Care AB  
Box 13080  
Gamlestadsvägen 3C  
SE-402 52 Göteborg  
Sweden**

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 II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 01965

## Certificate Scope:

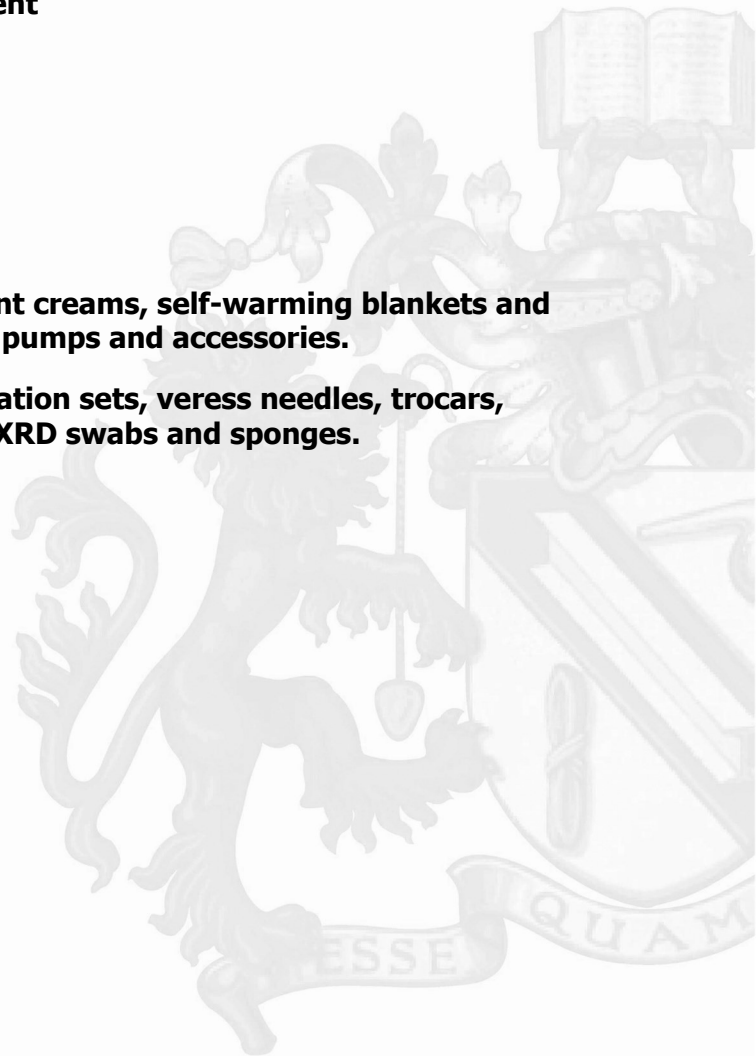
**The design and manufacture of sterile medicated and non-medicated open wound products:**

- **Adhesive bandage and dressing**
- **Exudate-absorbent dressing, hydrophilic-gel (alginate and gel fibre)**
- **Exudate-absorbent dressing, non-gel (absorbent, superabsorbent, foam)**
- **Semi-permeable film dressing, wound-nonadherent**
- **Semi-permeable film dressing**
- **Sterile wound irrigation solutions**
- **Wound-nonadherent dressing, absorbent**
- **Wound-nonadherent dressing, permeable**
- **Wound dressing with silver salt**
- **Wound dressing with sodium salt**
- **Wound dressing with porcine collagen**

**The design and manufacture of non-sterile emollient creams, self-warming blankets and negative pressure wound therapy (NPWT) system, pumps and accessories.**

**The design and manufacture of sterile suction irrigation sets, veress needles, trocars, laparoscopic instruments, endo retrieval pouches, XRD swabs and sponges.**

**The manufacture of sterile surgical gloves.**

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

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# 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

Latest Revision Date: 2018-11-26

Effective Date: 2018-11-28

Expiry Date: 2021-11-27



003

Page: 1 of 2

...making excellence a habit.™

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

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

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 are 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 LVFS 2009:18.

|                                      |                         |
|--------------------------------------|-------------------------|
| <b>Trade name/<br/>Product name:</b> | <b>Mepilex Transfer</b> |
|--------------------------------------|-------------------------|

**Product classification:** **IIb**

**Sterility:** **EtO**

**Measuring function:** **No**

|                                                                                       |           |
|---------------------------------------------------------------------------------------|-----------|
| This declaration is supported by a conformity assessment procedure in accordance with |           |
| <b>Annex/es:</b>                                                                      | <b>II</b> |

|                            |                 |
|----------------------------|-----------------|
| <b>Certificate number:</b> | <b>CE 01965</b> |
|----------------------------|-----------------|

|                   |                 |
|-------------------|-----------------|
| <b>Issued by:</b> | <b>BSI 0086</b> |
|-------------------|-----------------|

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

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

**Date:** **2010-08-18**

**Function:** **RA Director Operations**

**Name:** **Anders Edner**

**Signature:**



**Product(s) covered by this declaration:**

| <b>Product Reference:</b> | <b>Product Descriptor:</b>              |
|---------------------------|-----------------------------------------|
| 294502                    | Soft silicone exudate transfer dressing |
| 294600                    | Soft silicone exudate transfer dressing |
| 294621                    | Soft silicone exudate transfer dressing |
| 294700                    | Soft silicone exudate transfer dressing |
| 294720                    | Soft silicone exudate transfer dressing |
| 294800                    | Soft silicone exudate transfer dressing |
| 294920                    | Soft silicone exudate transfer dressing |

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the manufacturer of the following, declare that the devices listed in the attached schedule are 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 LVFS 2009:18.

|                                      |                                                    |
|--------------------------------------|----------------------------------------------------|
| <b>Trade name/<br/>Product name:</b> | <b>Mepilex Lite Products / Mepilex EM Products</b> |
|--------------------------------------|----------------------------------------------------|

**Product classification:** **IIb**

**Sterility:** **EtO**

**Measuring function:** **No**

|                                                                                       |           |
|---------------------------------------------------------------------------------------|-----------|
| This declaration is supported by a conformity assessment procedure in accordance with |           |
| <b>Annex/es:</b>                                                                      | <b>II</b> |

|                            |                 |
|----------------------------|-----------------|
| <b>Certificate number:</b> | <b>CE 01965</b> |
|----------------------------|-----------------|

|                   |                 |
|-------------------|-----------------|
| <b>Issued by:</b> | <b>BSI 0086</b> |
|-------------------|-----------------|

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

Mölnlycke Health Care issues this declaration in recognition of all applicable harmonised standards.

Signed for and on behalf of Mölnlycke Health Care

**Date:** **2011-01-04**

**Function:** **RA Director Operations**

**Name:** **Anders Edner**

**Signature:**



**Product(s) covered by this declaration:**

| Product Reference: | Product Descriptor:              |
|--------------------|----------------------------------|
| 284000             | Absorbent soft silicone dressing |
| 284021             | Absorbent soft silicone dressing |
| 284022             | Absorbent soft silicone dressing |
| 284040             | Absorbent soft silicone dressing |
| 284100             | Absorbent soft silicone dressing |
| 284121             | Absorbent soft silicone dressing |
| 284122             | Absorbent soft silicone dressing |
| 284140             | Absorbent soft silicone dressing |
| 284300             | Absorbent soft silicone dressing |
| 284321             | Absorbent soft silicone dressing |
| 284322             | Absorbent soft silicone dressing |
| 284340             | Absorbent soft silicone dressing |
| 284500             | Absorbent soft silicone dressing |



# 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**



Page: 1 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. This certificate does not expire. An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +44 (0)20 8996 7033.

The British Standards Institution is incorporated by Royal Charter.  
Management Systems (CEMEA) Headquarters: 389 Chiswick High Road, London, W4 4AL, United Kingdom



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 Wareme  
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**

Page: 2 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. This certificate does not expire. An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +44 (0)20 8996 7033.

The British Standards Institution is incorporated by Royal Charter.  
Management Systems (CEMEA) Headquarters: 389 Chiswick High Road, London, W4 4AL, United Kingdom

Certificate No: **FM 39247**

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

Page: 3 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. This certificate does not expire. An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +44 (0)20 8996 7033.

The British Standards Institution is incorporated by Royal Charter.  
Management Systems (CEMEA) Headquarters: 389 Chiswick High Road, London, W4 4AL, United Kingdom

## 284322 Mepilex EM

Absorbent soft silicone dressing

### Product details

**Size :** 17.5cm x 17.5cm  
**Descriptive feature :** Foam, Non-border, Soft silicone, Thin  
**Sterile :** Sterile

### Images



### Delivered items

284322-01

**Sales released in:** Bosnia and Herzegovina, Bulgaria, Croatia, France, Greece, Hungary, Israel, Macedonia (the former Yugoslav Republic of), Martinique, Moldova (the Republic of), Pakistan, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Turkey

**Country of origin:** Finland

**Shelf life:** 3 years

**Sterilization method:** EtO

**Packing information:** First packaging layer is a peel open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a cardboard dispenser box. Third layer is a corrugated board transport box.

**Is suitable for Tray:** No

| Packing level | Quantity | GS1 code      | WxLxH (mm)  | Vol (dm <sup>3</sup> ) | Weight gross/net (kg) |
|---------------|----------|---------------|-------------|------------------------|-----------------------|
| Consumer pack | 1        | 7332430666642 |             |                        |                       |
| Dispenser box | 5        | 7323190126606 | 26x220x236  |                        |                       |
| Transport box | 35       | 7323190126590 | 234x263x215 | 13.2                   | 1.3 / 0.5             |

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.  
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.  
©2020 Mölnlycke Health Care AB. All rights reserved.



| Packing level | Quantity | GS1 code      | WxLxH (mm)    | Vol (dm <sup>3</sup> ) | Weight gross/net (kg) |
|---------------|----------|---------------|---------------|------------------------|-----------------------|
| Pallet        | 4200     | 7323190126583 | 800x1200x1884 |                        |                       |

## Material

**Animal tissues :** No  
**Natural rubber latex :** No  
**Medicinal substances :** No

## Product Composition Non-bordered Foam Products

| Product Component        | Composition       |
|--------------------------|-------------------|
| Backing material         | Polyurethane film |
| Wound pad                | Polyurethane foam |
| Wound contact layer      | Silicone          |
| Protective release liner | Polyethylene film |

## Product Performance Non-bordered Foam Products

| Characteristics                                                                                | Test Method         | Internal Test Method | Unit                       | Requirement   | Product Performance |
|------------------------------------------------------------------------------------------------|---------------------|----------------------|----------------------------|---------------|---------------------|
| Free Swell Absorptive Capacity                                                                 | EN 13726-1 part 3:2 | T-1069               | g/100 cm <sup>2</sup>      | Not specified | N/A                 |
| Free Swell Absorptive Capacity                                                                 | EN 13726-1 part 3:2 | T-1069               | g/g                        | Not specified | N/A                 |
| Fluid Handling Capacity                                                                        | EN 13726-1 part 3:3 | T-1068               | g/10 cm <sup>2</sup> /24 h | Not specified | 7.3                 |
| Absorbency                                                                                     | EN 13726-1 part 3:3 | T-1068               | g/10 cm <sup>2</sup> /24 h | Not specified | 1.82                |
| Moisture Vapour Transmission Rate (MVTR)                                                       | EN 13726-1 part 3:3 | T-1068               | g/10 cm <sup>2</sup> /24 h | Not specified | 5.5                 |
| Moisture Vapour Transmission Rate (MVTR) of a wound dressing when in contact with water vapour | EN 13726-2 part 3:2 | T-1070               | g/m <sup>2</sup> /24 h     | Not specified | 2282                |

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.  
 The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.  
 ©2020 Mölnlycke Health Care AB. All rights reserved.



| Characteristics                                                                          | Test Method         | Internal Test Method | Unit                   | Requirement                        | Product Performance |
|------------------------------------------------------------------------------------------|---------------------|----------------------|------------------------|------------------------------------|---------------------|
| Moisture Vapour Transmission Rate (MVTR) of a wound dressing when in contact with liquid | EN 13726-2 part 3:3 | T-1075               | g/m <sup>2</sup> /24 h | Not specified                      | 4617                |
| Waterproofness                                                                           | EN 13726-3          | T-1083               | Pass/Fail              | >500 mm H <sub>2</sub> O for 300 s | N/A                 |
| Conformability-Extensibility, MD                                                         | EN 13726-4          | T-1086               | N/cm                   | Not specified                      | 0.6                 |
| Conformability-Extensibility, CD                                                         | EN 13726-4          | T-1086               | N/cm                   | Not specified                      | 0.5                 |
| Conformability-Permanent Set, MD                                                         | EN 13726-4          | T-1086               | %                      | Not specified                      | 0.3                 |
| Conformability-Permanent Set, CD                                                         | EN 13726-4          | T-1086               | %                      | Not specified                      | 2.7                 |
| Resistance to microbial penetration - Wet                                                | ISO 22610           | T-1005               | BI                     | 6                                  | N/A                 |
| Viral penetration                                                                        | ASTM F 1671         | N/A                  | Pass/Fail              | 29 out of 32 samples               | N/A                 |

#### Technical

#### Dimension

| Dimension text | Dimension value   |
|----------------|-------------------|
| Product        | 17.5 cm x 17.5 cm |
| Product        | 6.9 in x 6.9 in   |

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.  
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.  
©2020 Mölnlycke Health Care AB. All rights reserved.



## Classifications

| Regulation type(s)                  | MDD Class IIb                                                                                                                                                                                                                                                                                        | Locally Regulated                                                                   | Unregulated                                 |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------|
| MDD Classification Rule :           | 4                                                                                                                                                                                                                                                                                                    |                                                                                     |                                             |
| CE Certificate Number :             | CE 01965                                                                                                                                                                                                                                                                                             |                                                                                     |                                             |
| Notified body medical devices/PPE : | BSI (2797)                                                                                                                                                                                                                                                                                           |                                                                                     |                                             |
| Intended use MDD :                  | Mepilex Lite is designed for the management of a wide range of non to low exuding wounds, such as leg and foot ulcers, pressure ulcers, partial thickness burns, radiation skin reactions and Epidermolysis Bullosa. Mepilex Lite can also be used as protection of compromised and/or fragile skin. |                                                                                     |                                             |
| Sales released in :                 | Bulgaria, Croatia, France, Greece, Hungary, Martinique, Poland, Portugal, Romania, Slovakia, Slovenia, Spain                                                                                                                                                                                         | Bosnia and Herzegovina, Israel, Moldova (the Republic of), Pakistan, Serbia, Turkey | 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 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, EN ISO 10993-11, EN ISO 10993-10, EN ISO 10993-18, ISO 14001

## Removable label

No

## GMDN Code (Global Medical Device Nomenclature)

46854 Wound - nonadherent dressing, absorbent, sterile

## UNSPSC

42311510 Foam dressings

## Commodity Code

3005100000 Wadding, Gauze, Dressings, drapes singlepacked - adhesive articles, Sets mainly consisting thereof

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.  
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.  
©2020 Mölnlycke Health Care AB. All rights reserved.



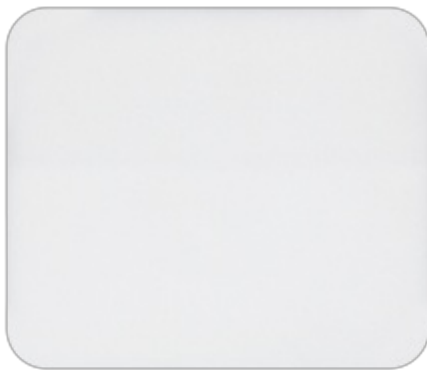
## 294502 Mepilex Transfer

Soft silicone exudate transfer dressing

### Product details

**Size :** 20cm x 50cm  
**Descriptive feature :** Exudate transfer, Foam, Non-border, Soft silicone  
**Sterile :** Sterile

### Images



### Delivered items

294502-03

**Sales released in:** Algeria, Australia, Austria, Bahrain, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Canada, China, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Iran (Islamic Republic of), Ireland, Israel, Italy, Japan, Kazakhstan, Kuwait, Latvia, Lithuania, Luxembourg, Macedonia (the former Yugoslav Republic of), Malaysia, Moldova (the Republic of), Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan (Province of China), Thailand, Turkey, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland

**Country of origin:** Finland

**Shelf life:** 3 years

**Sterilization method:** EtO

**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 cardboard dispenser box. Third layer is a corrugated board transport box.

**Is suitable for Tray:** No

| Packing level | Quantity | GS1 code      | WxLxH (mm) | Vol (dm <sup>3</sup> ) | Weight gross/net (kg) |
|---------------|----------|---------------|------------|------------------------|-----------------------|
| Consumer pack | 1        | 7332430003775 |            |                        |                       |

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.  
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.  
©2020 Mölnlycke Health Care AB. All rights reserved.



| Packing level | Quantity | GS1 code      | WxLxH (mm) | Vol (dm <sup>3</sup> ) | Weight gross/net (kg) |
|---------------|----------|---------------|------------|------------------------|-----------------------|
| Dispenser box | 4        | 7323190024032 |            |                        |                       |
| Transport box | 24       | 7323190024025 |            |                        |                       |
| Pallet        | 2016     | 7323190024018 |            |                        |                       |

Material

Natural rubber latex : No

### Product Composition Wound Contact Layers

| Product Component        | Composition       |
|--------------------------|-------------------|
| Transferring layer       | Polyurethane foam |
| Wound contact layer      | Silicone          |
| Protective release liner | Polyethylene film |

### Product Performance Wound Contact Layer Products

| Characteristics                  | Test Method         | Internal Test Method | Unit                  | Requirement   | Product Performance |
|----------------------------------|---------------------|----------------------|-----------------------|---------------|---------------------|
| Free Swell Absorptive Capacity   | EN 13726-1 part 3:2 | T-1069               | g/100 cm <sup>2</sup> | Not specified | N/A                 |
| Free Swell Absorptive Capacity   | EN 13726-1 part 3:2 | T-1069               | g/g                   | Not specified | N/A                 |
| Conformability-Extensibility, MD | EN 13726-4          | T-1086               | N/cm                  | Not specified | N/A                 |
| Conformability-Extensibility, CD | EN 13726-4          | T-1086               | N/cm                  | Not specified | N/A                 |
| Conformability-Permanent Set, MD | EN 13726-4          | T-1086               | %                     | Not specified | N/A                 |
| Conformability-Permanent Set, CD | EN 13726-4          | T-1086               | %                     | Not specified | N/A                 |

Technical

### Dimension

| Dimension text | Dimension value |
|----------------|-----------------|
| Product        | 20 cm x 50 cm   |

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.  
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.  
©2020 Mölnlycke Health Care AB. All rights reserved.



| Dimension text | Dimension value |
|----------------|-----------------|
| Product        | 8 in x 20 in    |

## Classifications

| Regulation type(s)                  | MDD Class IIb                                                                                                                                                                                                                                                                                                                          | Locally Regulated                                                                                                                                                                                                                                                                                              | Unregulated                                                                          |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| CE Certificate Number :             | CE 01965                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                |                                                                                      |
| Notified body medical devices/PPE : | BSI (2797)                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                |                                                                                      |
| Intended use MDD :                  | Mepilex Transfer is designed for a wide range of exuding and difficult-to-dress wounds. Mepilex Transfer can also be used as a protective layer on non-exuding wounds and/or large areas of fragile skin. Mepilex Transfer can be used under compression.                                                                              |                                                                                                                                                                                                                                                                                                                |                                                                                      |
| Sales released in :                 | Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland | Algeria, Australia, Bahrain, Canada, China, Israel, Japan, Kazakhstan, Kuwait, Macedonia (the former Yugoslav Republic of), Malaysia, Moldova (the Republic of), New Zealand, Russian Federation, Saudi Arabia, Serbia, Singapore, Taiwan (Province of China), Thailand, Turkey, Ukraine, United Arab Emirates | Belarus, Bosnia and Herzegovina, Hong Kong, Iran (Islamic Republic of), South Africa |

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

EN 1041, 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, EN ISO 10993-11, EN ISO 10993-10, EN ISO 10993-18, ISO 14001

## Removable label

No

## GMDN Code (Global Medical Device Nomenclature)

46855 Wound - nonadherent dressing, permeable

Find out more at [www.molnlycke.com](http://www.molnlycke.com)

Mölnlycke Health Care AB, Box 13080, Gamlestadsvägen 3 C, SE-402 52 Göteborg, Sweden. Phone +46 31 722 30 00.  
The Mölnlycke trademarks, names and logotypes are registered globally to one or more of the Mölnlycke Health Care Group of Companies.  
©2020 Mölnlycke Health Care AB. All rights reserved.



# REPORT OF EXPERIENCES:

Atraumatic Dressings in Fragile Skin Conditions: Use of the Soft Silicone Dressing (Mepilex®) in Hereditary and Acquired Bullous Skin Diseases.

**Hauke Schumann M.D.**

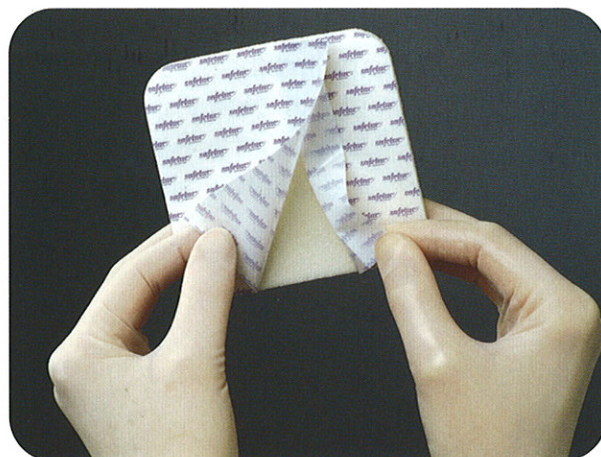
**Gabriele Beljan M.D.**

**Doris Höping**

**Prof. Leena Bruckner-Tuderman M.D.**

Department of Dermatology,

University Hospital Muenster, Germany



## Soft silicone dressing

Here we present our experience with the absorbent soft silicone dressing (Mepilex) in wound management of patients with hereditary and acquired fragile skin conditions. Twenty-two patients seen as out- or inpatients were evaluated. Thirteen patients suffered from recurrent blistering caused by hereditary epidermolysis bullosa (EB), nine from acquired bullous diseases including bullous pemphigoids, pemphigus vulgaris, EB acquisita, subcorneal pustulosis, toxic contact dermatitis and blistering as a result of radiation therapy. The age of the patients spanned from 1 to 91 years.

## Wound healing

To assess its capacity to influence wound healing and to protect lesional skin from further blistering Mepilex was applied to pressure areas like elbows, knees and feet and to other areas with chronic or acute wounds.

The patients/parents gave informed consent to apply Mepilex as a wound care product. Patients, parents of young children and nurses were instructed how to use the soft silicone dressing. The wounds were cleaned with skin disinfectants e.g. 0,1% Lavasept (Polyhexanid) or Octenisept (Octinidinhydrochlorid 0,1% - Phenoxyethanol 2%) and Mepilex was directly applied onto the wounds. It was recommended to change dressings daily in order to check for blistering, signs of infection and to exclude adverse events. However, some patients left the dressing for up to five days.

In most cases Mepilex had to be fixated with conventional bandages. The size of the assessed lesions was measured before the first application of Mepilex. Secretion, epithelialization, inflammation were documented, viable and non viable tissue was estimated before the first application, at each clinical visit and at the end of the treatment. At each visit photos were taken.

## Results

We observed good wound healing of acute and chronic wounds, with fast epithelialization in most cases. Mepilex showed good capacity to absorb wound secretion. The soft silicone adhesive layer did not tear the EB skin and only in one case of an acute eruptive pemphigus vulgaris did the Mepilex dressing remove the epidermis when it was changed. No allergic reactions were observed.

After complete reepithelialization Mepilex can protect pressure points like knees, elbows, shoulders from mechanically induced painful lesions, especially in children with EB. However new blisters can occur under the dressing and these needs to be treated. Most patients with hereditary EB continuously develop blisters. Eleven out of 13 EB patients added Mepilex to their standard wound dressing products. Especially EB patients with restricted ability to change dressings by themselves used Mepilex as an “easy to handle” product which could be changed without assistance.

However, patients need to be instructed that careful inspection of the wound to exclude e.g. wound infection is as important as sterile drainage of blisters that occur under the Mepilex dressing. As with every other dressing, unfrequent dressing changes can result in adverse events.

## Positive remarks

- Good wound healing and epithelialization
- Excellent protection and padding
- Good absorption
- Atraumatic to wound bed
- No or little pain during dressing changes
- No allergic reactions
- Easy to handle
- Independent wound care
- Removal of crusts when combined e.g. with creams or gels

## **Problematic aspects**

- Softening of wound edges
- Initial spreading of wound borders
- Can be too adhesive in acute eruptive phase of pemphigus
- “Easy to handle” might lead to unreflected long term application
- Ulceration, superinfection and hypergranulation under unreflected long term application
- In incontinent patients the dressing might absorb urine

## **Frequent EB patients’ comments**

- Good healing
- Good protection
- Good absorption
- Easy to handle

## **Conclusion**

The application of soft silicone dressings like Mepilex in acute and chronic wounds in fragile skin conditions shows good wound healing, epithelialization, protection and it can be used as an “easy to handle” dressing. Strong secretion from wounds in bullous diseases can result in initial softening at the wound edges under Mepilex before reepithelialization starts. Since Mepilex is much easier to handle than many other wound dressings some patients tended to unreflected long term use which can cause adverse effects. Dressing changes every 4<sup>th</sup> or 5<sup>th</sup> day can result in ulceration and widening of wounds. Therefore especially when wounds are infected, daily dressing changes and careful cleaning before application are required.

In acute phases of superficial blistering or in newborns with extremely fragile skin the adhesive effect might be too strong and the product should be handled with care.

## Figure legends

### Patient 1:

An acute erosion after mechanically induced blistering under the right foot of a patient with EB acquisita (A) showed complete epithelialization within 4 weeks (B). To protect from shearing forces Mepilex was used as a “dressing shoe” after the initial lesion healed (C). Mepilex was fixed with a cohesive conforming bandage.



Patient 1A



Patient 1B



Patient 1C

### Patient 2:

Blistering of the lower arm in bullous pemphigoid (A). Good wound healing and epithelialization under Mepilex. However, new blisters occurred under the dressing in the early phase of the therapy, but blister roofs were not removed by the dressing change (B). Wound secretion was absorbed by Mepilex (C).



Patient 2A



Patient 2B



Patient 2C

### **Patient 3:**

Chronic wounds at the shoulders of a teenager with EB showed good wound healing under Mepilex. It was protective and easy to handle (A). Circular incision of the Mepilex dressing allowed adaption to this region (B). However, careful wound cleaning and dressing changes every day in infected superficial wounds are important in order to avoid adverse events.



Patient 3A



Patient 3B

### **Patient 4:**

Bullosis diabeticorum and consecutive diabetic ulcer (A). Good absorption, wound healing and reduction of shearing forces at a pressure point of the lateral left foot (B).



Patient 4A



Patient 4B