

gyártó neve

Lunor AG  
Lunor Allee 1  
75378 Bad Liebenzell  
Germany

Single Registration Number (SRN)

DE-MF-000022117

Egyedüli felelősként kijelentjük, hogy a termék

terméknév név

szemüvegkeretek / modelleket lásd melléklet

Basic UDI-DI

lásd a függelék

Nómenklatúrája

GMDN Code 32816, EMDN Code lásd a függelék

kockázati osztály

I. osztály - nem steril, nincs mérési funkció

Megfelelőségértékelési eljárások

az 52. cikk (7) bekezdés szerint orvostechnikai eszközre

a következő jogi előírások rendelkezéseinek megfelel:

Az Európai Parlament és a Tanács (EU) 2017/745 rendelete az orvostechnikai eszközökről

1907/2006/EK rendelete a vegyi anyagok regisztrálásáról, értékeléséről, engedélyezéséről és korlátozásáról (REACH))

az EN ISO 12870 Európai Normának megfelel

A termék forgalomba hozatala utáni ellenőrzésére szisztematikus eljárást tartunk fenn.

Bad Liebenzell, 09.01.2025

a kiállítás helye és dátuma

  
Michael Fux  
ügyvezetés

  
Maria Pietsch  
MDR felelős személy



**MELLÉKLET**

| <b>Vonal</b>  | <b>Modell</b>                                                        | <b>Színes</b>                                                       | <b>Basic UDI-DI</b>       | <b>EMDN Code</b> |
|---------------|----------------------------------------------------------------------|---------------------------------------------------------------------|---------------------------|------------------|
| M2            | 01,02                                                                | AG,AS,RGS                                                           | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 01 Asia, 02 Asia                                                     | AG,AS,GP,PP                                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
| M5            | 01,02,03                                                             | AG,AS,GP,PP                                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 04,05,06,07                                                          | AG,AS,GP,PP,SWS                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 04,05,06                                                             | RGS                                                                 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 08                                                                   | AG,AS,RGS                                                           | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
| M6            | 02,04,05,06                                                          | AG,AS,RGS                                                           | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
| M9            | 01                                                                   | AG,AG BR,AS,AS BL,BG,CBS,GG,GP,H<br>S, NBS,PP,PPS,RG,RGS,RGS GN,SWS | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 02                                                                   | AG,AG BR,AS,AS BL,GP,PP,RG,RGS,<br>RGS GN,SWS                       | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 03                                                                   | AG,GP,PP,RG,RGS                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 04                                                                   | AS,GP,PP,RG,SWS                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 05,06                                                                | GP,PP,RG                                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 07                                                                   | AS, RGS,SWS                                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 08                                                                   | AG BR,AS, AS BL,RGS,RGS GN,SWS                                      | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               |                                                                      |                                                                     |                           |                  |
| M10           | 01                                                                   | AG,AS,GP,PP,RG,RGS,PPS BL,<br>RGS GN,SWS                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 02,03,04                                                             | AG,AS,GP,PP,RG,RGS                                                  | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 05,06                                                                | AG,AS,RGS                                                           | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 08                                                                   | AG,AS,PPS BL,RGS,RGS GN,SWS                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
| M11           | 01                                                                   | AG,RGS                                                              | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 02,03,04                                                             | AG,AS,RGS                                                           | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
| M12           | 01,02                                                                | GP,GPS,PP,PPS,BR,BRS                                                | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
| M13           | 01,02                                                                | AG,AS,BL,PP,RG,SWS                                                  | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 04                                                                   | AG,AS,SWS                                                           | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
| M14           | 01,02,03,04,05                                                       | AG,AS,PPS,RGS,SGS,SWS                                               | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
| M14           | 02,03                                                                | AG,AS,PPS                                                           | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
| M16           | 01,02                                                                | BBS,BLS,EBS,GOS,GPS,PPS,PRS,SWS                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|               | 03,04                                                                | BBS,BLS,EBS,GPS,PPS,PRS                                             |                           |                  |
| Classic       | Kronenpanto,<br>Octagon, Oval M,<br>Panatomic, Panto<br>M, Anatom. M | AG,AS,GP,PP                                                         | 4054514FRA-MIX-LESS-ADLGK | Q02100203        |
|               | Rund                                                                 | AG,AS,GP,PP,RGS,SWS                                                 | 4054514FRA-MIX-LESS-ADLGK | Q02100203        |
|               | Rund M                                                               | AG,AS                                                               | 4054514FRA-MIX-LESS-ADLGK | Q02100203        |
|               |                                                                      |                                                                     |                           |                  |
| Classic 18kt. | Rund                                                                 | G,G mit Pads                                                        | 4054514FRA-MIX-LESS-ADLGK | Q02100203        |
|               |                                                                      | W,W mit Pads                                                        | 4054514FRA-MIX-LESS-ADLGK | Q02100203        |



|            |             |                                                                                                       |                           |           |
|------------|-------------|-------------------------------------------------------------------------------------------------------|---------------------------|-----------|
| Combi II   | 81          | AG,ASB,ASH,BR,PP                                                                                      | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| Combi II A | 23          | ASB,DG,PP,PPH                                                                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 24,25       | AS,AG,ASB,DG,PP,PPH                                                                                   | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| C1         | 01,02,03,04 | AG,AS,RGS                                                                                             | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| C3         | 01, 02      | 03mGPS,01mPPS,04mRGS,18mPPS,<br>02mRGS                                                                | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| A5         | 215         | 01,02,03,04,05,06,14,15,16,17,18,20,<br>23,36,37,38,40,41,42,55,56,01M,<br>02M,03M,18M,26M,56M        | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 226         | 01,02,03,04,05,06,14,15,16,17,18,20,<br>23,36,37,38,40,41,42,55,56,01M,<br>02M,03M,18M,26M,56M,85,85M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 230         | 01,02,03                                                                                              | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 231         | 01,02,03,14,15,16,17,18,40,41,42,55,<br>56,01M,02M,03M,18M,26M,56M85,<br>85M                          | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 232         | 01,02,03,05,06,18,40,41,42,01M,<br>02M,03M,18M,26M                                                    | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 234         | 01,02,03,05,06,14,15,16,17,18,36,37,<br>38,40,41,42,55,56,01M,02M,03M,<br>18M,26M,55M,56M,85,85M      | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 237         | 01,02,03,40,41,02M,03M                                                                                | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 238         | 01,02,03,18,41,56,01M,02M,03M,<br>18M,26M                                                             | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 239         | 01,02,03,40,41,42,01M,02M,03M                                                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 600         | 01,02,03,36,37,38,53,54,55                                                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 601         | 01,02,03,14,15,36,37,38,55,56,85                                                                      | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 602         | 01,02,03,36,37,38,53,54,55                                                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 603         | 01,02,03,36,37,38,40,41,53,54,55,85                                                                   | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 604         | 01,02,03,14,15,18                                                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 605         | 01,02,03,15,40,41,56,01M,02M,03M,<br>15M,18M,26M,41M,56M85M                                           | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 607         | 01,02,15,41,55,56,01M,02M,15M,<br>26M,55M,56M                                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 610         | 01,02,15,41,55,56,85,01M,02M,15M,<br>26M,56M,85M                                                      | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 612         | 01,02,15,40,41,85                                                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| A6         | 244         | 01,02,03,04,18,33,01M,02M,03M,<br>18M,26M                                                             | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 246         | 01,02,03,04,18,33,40,41,42,56,01M,<br>02M,03M,18M,26M, 56M                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 249         | 01,02,40,41,42,01M,02M,03M                                                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|            | 250         | 01,02,18,33,40,41,42,56,01M,02M,<br>03M,18M,26M,56M                                                   | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |



|     |     |                                                              |                           |           |
|-----|-----|--------------------------------------------------------------|---------------------------|-----------|
|     | 251 | 01,02,03,40,41,42,56,01M,02M,03M,<br>18M,26M,56M             | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 252 | 01,02,01M,02M,03M                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 255 | 01,02,33,01M,02M,26M                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 256 | 01,02,33,40,41,42,56,01M,02M,03M,<br>18M,26M,56M             | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 257 | 01,02,33,40,41,56                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 258 | 01,02,33,40,41,56                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| A10 | 350 | 32,44,45,46                                                  | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 352 | 03,18,31,45                                                  | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 353 | 43,45,46                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 354 | 02,03,18,30,31,32                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 355 | 02,03,18,30,31,32                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| A11 | 450 | 02,03,18,30,31,32,31M,32M                                    | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 451 | 02,03,14,15,18,30,31,32,57,58,59,<br>30M,31M,32M             | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 452 | 01,02,03,14,15,18,30,31,32,57,58,59,<br>82,83,84,30M,31M,32M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 453 | 02,03,14,15,18,30,31,32,57,59,30M,<br>31M,32M                | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 454 | 01,02,03,30,31,32                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 455 | 02,18,30,32,57,59,30M,32M                                    | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 456 | 01,02,03,30,31,32,57,58,59                                   | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 457 | 01,02,15,30,32,82,83,84,30M,32M                              | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 458 | 02,15,30M,32M                                                | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 459 | 01,02,15,30,32,30M,32M,76M,77M,<br>78M                       | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 460 | 01,02,15,76M,77M,78M                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 461 | 01,02,15,79,80,81                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 462 | 01,02,15,79,80,81                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| A12 | 500 | 01,02,15,01M,02M,15M,61,62                                   | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 501 | 01,02,15,61,62,63,64,65,66,67,68,70,<br>71,72, 01M,02M,15M   | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 502 | 01,02,01M,02M,15M                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 503 | 01,02,15,01M,02M,15M                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 504 | 01,02,15,                                                    | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 505 | 01,02,15,                                                    | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 506 | 01,02,15,                                                    | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 507 | 01,02,15,61,62,66,67,68                                      | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 508 | 01,02,15,63,64,65,66,67,68,70,71,72                          | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 509 | 01,02,15,63,64,65,66,67,68,70,71,72                          | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 510 | 01,02,15,70,71,72                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 511 | 01,02,15,63,64,65                                            | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| A13 | 550 | 50,51,52                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 551 | 50,51,52                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 552 | 50,51,52                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 553 | 50,51,52                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 554 | 50,51,52                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|     | 555 | 50,51,52                                                     | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |



|     |        |                   |                               |           |
|-----|--------|-------------------|-------------------------------|-----------|
| A14 | 700    | 01,02,15,73,74,75 | 4054514FRA-MIX-FULL-ADLG9     | Q02100203 |
|     | 701    | 01,02,15,73,74,75 | 4054514FRA-MIX-FULL-ADLG9     | Q02100203 |
|     | 702    | 01,02,15,73,74,75 | 4054514FRA-MIX-FULL-ADLG9     | Q02100203 |
|     | 703    | 01,02,15,73,74,75 | 4054514FRA-MIX-FULL-ADLG9     | Q02100203 |
|     | 704    | 01,02,15,73,74,75 | 4054514FRA-MIX-FULL-ADLG9     | Q02100203 |
|     | 705    | 01,02,15,73,74,75 | 4054514FRA-MIX-FULL-ADLG9     | Q02100203 |
| B1  | 01, 02 | 501,502,503,504   | 4054514FRA-OTH-FULL-<br>ADLEQ | Q02100299 |
|     | 03,04  | 501, 502          | 4054514FRA-OTH-FULL-<br>ADLEQ | Q02100299 |