



Naziv proizvođača

**Lunor AG**  
**Lunor Allee 1**  
**75378 Bad Liebenzell**  
**Germany**

Single Registration Number (SRN)

**DE-MF-000022117**

Samostalnom odgovornošću izjavljujemo da proizvod

ime proizvoda

**Okviri za naočale / Modeli, vidi Prilog**

Basic UDI-DI

**vidi Prilog**

Nomenklatura

**GMDN Code 32816, EMDN Code vidi Prilog**

Kategorija rizika

**Kategorija I – nije sterilno, bez funkcije mjerenja**

Postupci ocjenjivanja sukladnosti

**u skladu s člankom 52 (7) za medicinske proizvode**

odgovara odredbama sljedećih pravnih propisa:

Uredba (EU) 2017/745 Europskog parlamenta i Vijeća o medicinskim proizvodima

Uredba (EZ) br. 1907/2006 o registraciji i odobrenju i ograničavanje kemikalija (REACH)

Odgovara Europskoj normi EN ISO 12870

Koristimo sustavni postupak za nadzor proizvoda nakon puštanja na tržište.

**Bad Liebenzell, 18.08.2025**

Mjesto i datum izdavanja

**Michael Fux**  
Poslovodstvo

**Maria Pietsch**  
MDR Odgovorna osoba



**PRILOG**

| <b>Crta</b> | <b>Model</b>                                                | <b>Boja</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                                                       | AG,AS,GP,PP                                                         | 4054514FRA-MIX-FULL-ADLG9 | Q02100203        |
|             | 03                                                          | AG,AS,GP,PP,RGS                                                     | 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,<br>Anatom. M | AG,AS,GP,PP                                                         | 4054514FRA-MIX-LESS-ADLGK | Q02100203        |
|             | Panto M                                                     | AG,AS,GP,PP,RGS                                                     | 4054514FRA-MIX-LESS-ADLGK | Q02100203        |
|             | Modern Panto                                                | AG,AS,RGS                                                           | 4054514FRA-MIX-LESS-ADLGK | Q02100203        |
|             | Rund                                                        | AG,AS,GP,PP,RGS,SWS                                                 | 4054514FRA-MIX-LESS-ADLGK | Q02100203        |



|               |             |                                                                                                                        |                           |           |
|---------------|-------------|------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------|
|               | Rund M      | GP,PP,RGS,SWS                                                                                                          | 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>23,36,37,38,40,41,42,55,56,86,87,88,<br>89,90,91,01M,<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>38,40,41,42,55,56,86,87,88,89,90,91,<br>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,<br>86,87,88,89,90,91                                                              | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|               | 604         | 01,02,03,14,15,18                                                                                                      | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
|               | 605         | 01,02,03,15,40,41,56,86,87,88,01M,0<br>2M,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 |



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|-----|-----|--------------------------------------------------------------|---------------------------|-----------|
| 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,40M,41M,56M,85M | 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,40M,41M,56M,85M | 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 |
|     | 259 | 01,02,41,01M,02M,85M                                         | 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 |
|     | 513    | 01,02,15,63,70,71 | 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 |
|     | 706    | 01,02,15,73,74,75 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| B1  | 01, 02 | 501,502,503,504   | 4054514FRA-OTH-FULL-ADLEQ | Q02100299 |
|     | 03,04  | 501, 502          | 4054514FRA-OTH-FULL-ADLEQ | Q02100299 |