



Imię producenta

Lunor AG
Lunor Allee 1
75378 Bad Liebenzell
Germany

Single Registration Number (SRN)

DE-MF-000022117

Z pełną odpowiedzialnością oświadczamy, iż produkt

Nazwa produktu

oprawki do okularów / modele zobacz załącznik

Basic UDI-DI

patrz załącznik

Nomenklatura

GMDN Code 32816, EMDN Code patrz załącznik

Klasa ryzyka

Klasa I – niesterylne, brak funkcji pomiarowej

Procedury oceny zgodności

których mowa w artykule 52 (7) dotyczące wyrobów medycznych

jest zgodny z przepisami następującego prawodawstwa:

Rozporządzenie Parlamentu Europejskiego i Rady (UE) 2017/745 z w sprawie wyrobów medycznych

Rozporządzenie (WE) nr 1907/2006 w sprawie rejestracji, oceny, udzielania zezwoleń i stosowanych ograniczeń w zakresie chemikaliów (REACH)

Zgodność z normą europejską EN ISO 12870

Prowadzimy procedurę systematycznego monitorowania produktu po wprowadzeniu go do obrotu.

Bad Liebenzell, 09.01.2025

Miejsce i data wydania

Michael Fux
Kierownictwo

Maria Pietsch
MDR osoba odpowiedzialna

ZAŁĄCZNIK

| <i>Linia</i> | <i>Model</i> | <i>Kolor</i> | <i>Basic UDI-DI</i> | <i>EMDN Code</i> |
|---------------|--|---|--|---------------------------|
| 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 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, 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, RGS GN,SWS | 4054514FRA-MIX-FULL-ADLG9 |
| 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, Octagon, Oval M, Panatomic, Panto 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 |

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| 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, 02mRGS | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |
| A5 | 215 | 01,02,03,04,05,06,14,15,16,17,18,20, 23,36,37,38,40,41,42,55,56,01M, 02M,03M,18M,26M,56M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |
| | 226 | 01,02,03,04,05,06,14,15,16,17,18,20, 23,36,37,38,40,41,42,55,56,01M, 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, 56,01M,02M,03M,18M,26M,56M85, 85M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |
| | 232 | 01,02,03,05,06,18,40,41,42,01M, 02M,03M,18M,26M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |
| | 234 | 01,02,03,05,06,14,15,16,17,18,36,37, 38,40,41,42,55,56,01M,02M,03M, 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, 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, 15M,18M,26M,41M,56M85M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |
| | 607 | 01,02,15,41,55,56,01M,02M,15M, 26M,55M,56M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |
| | 610 | 01,02,15,41,55,56,85,01M,02M,15M, 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, 18M,26M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | | 246 | 01,02,03,04,18,33,40,41,42,56,01M, 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, 03M,18M,26M,56M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |



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| | 251 | 01,02,03,40,41,42,56,01M,02M,03M, 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, 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, 30M,31M,32M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 452 | 01,02,03,14,15,18,30,31,32,57,58,59, 82,83,84,30M,31M,32M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 453 | 02,03,14,15,18,30,31,32,57,59,30M, 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, 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, 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 |



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| 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-ADLEQ | Q02100299 |
| | 03,04 | 501, 502 | 4054514FRA-OTH-FULL-ADLEQ | Q02100299 |