



Názov výrobcu

Lunor AG
Lunor Allee 1
75378 Bad Liebenzell
Germany

Single Registration Number (SRN)

DE-MF-000022117

Týmto prehlasujeme na vlastnú zodpovednosť, že výrobok

názov výrobku

Korekčné rámy na okuliare / Modely pozri príloha

Basic UDI-DI

pozri príloha

Názvoslovie

GMDN Code 32816, EMDN Code pozri príloha

Riziková trieda

Trieda I – nesterilné, žiadna meracia funkcia

Postupy posudzovania zhody

podľa článku 52 (7) pre medicínske produkty

zodpovedá ustanoveniam nasledujúcich právnych predpisov:

Nariadenie Európskeho parlamentu a Rady (EÚ) 2017/745 o zdravotníckych pomôckach

Rady (ES) č. 1907/2006 o registrácii, hodnotení, autorizácii a obmedzovaní chemických látok (REACH)

Zodpovedá európskej norme EN ISO 12870

Vykonávame systematické procesy kontrolujúce výrobok po jeho uvedení na trh.

Bad Liebenzell, 13.03.2024

Miesto a dátum zhotovenia

Michael Fux
Vedenie podniku

Maria Pietsch
MDR Zodpovedná osoba

PRÍLOHA

| Linija | Model | Barva | Basic UDI-DI | EMDN Code |
|---------------|--|--|--|---------------------------|
| 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 |
| M9 | 01 | AG,AG BR,AS,AS BL,CBS,GG,GP,NBS, PP,RG,RGS,RGS GN,SWS | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 02 | AG,AG BR,AS,AS BL,GP,PP,RG, 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 | | PPS BL,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,GOS,SWS | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| Classic | Kronenpanto, Octagon, Oval M, Panatomic, Panto M, Anatom. M | AG,AS,GP,PP | 4054514FRA-MIX-LESS-ADLGK | Q02100203 |
| | Rund | AG,AS,GP,PP,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 | PP,AG,ASB,ASH,BR | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| Combi II A | 23 | PP,ASB,PPH,DG | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 24,25 | PP,AS,AG,ASB,PPH,DG | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |

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|-----|-------------|--|--|---------------------------|-----------|
| 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 | 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,56M | 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 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |
| | 237 | 01,02,03, | 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, | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |
| | 602 | 01,02,03,36,37,38 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 | |
| | 603 | 01,02,03,36,37,38,53,54,55 | 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 | 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 | 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 | |
| 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 | |

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| 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 | 02,03,14,15,18,30,31,32,57,58,59, 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 | 02,15,30,32,30M,32M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 458 | 02,15,30M,32M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 459 | 02,15,30,32,30M,32M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | A12 | 500 | 01,02,15,01M,02M,15M,61,62 | 4054514FRA-MIX-FULL-ADLG9 |
| 501 | | 01,02,15,63,64,65,66,67,68, 01M,02M,15M,61,62 | 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 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| 509 | | 01,02,15,63,64,65,66,67,68 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| 510 | | 01,02,15 | 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 | 4054514FRA-MIX-FULL-ADLG9 |
| 701 | | 01,02,15 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| 702 | | 01,02,15 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| 703 | | 01,02,15 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| B1 | | 01, 02 | 501,502,503,504 | 4054514FRA-OTH-FULL- ADLEQ |
| | 03,04 | 501, 502 | 4054514FRA-OTH-FULL- ADLEQ | Q02100299 |