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| Όνομα του κατασκευαστή | Lunor AG Lunor Allee 1 75378 Bad Liebenzell Germany |
| Single Registration Number (SRN) | DE-MF-000022117 |
| Δηλώνουμε με αποκλειστική μας ευθύνη, ότι το προϊόν | |
| Ονομασία προϊόντος | Γυαλιά οράσεως / Μοντέλα βλέπε παράρτημα |
| Basic UDI-DI | βλέπε παράρτημα |
| Ονοματολογία | GMDN Code 32816, EMDN Code βλέπε παράρτημα |
| Κατηγορία κινδύνου | Κατηγορία I – μη αποστειρωμένο, καμία λειτουργία μέτρησης |
| Διαδικασίες εκτίμησης της συμμόρφωσης | σύμφωνα με το άρθρο 52 (7) για ιατροτεχνολογικά προϊόντα |

είναι σύμφωνο προς τις διατάξεις της ακόλουθης νομοθεσίας:

Κανονισμός (ΕΕ) 2017/745 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου για τα ιατροτεχνολογικά προϊόντα
ΚΑΝΟΝΙΣΜΟΣ (ΕΚ) αριθ 1907/2006 για την καταχώριση, την αξιολόγηση, την αδειοδότηση και τους περιορισμούς των
χημικών προϊόντων (REACH)

Πληροί το ευρωπαϊκό πρότυπο EN ISO 12870

Εφαρμόζουμε μια συστηματική διαδικασία εποπτείας του προϊόντος μετά τη θέση του σε κυκλοφορία.

Bad Liebenzell, 25.09.2023

Τόπος και ημερομηνία έκδοσης



Michael Fux
Διεύθυνση επιχείρησης



Maria Pietsch
MDR Υπεύθυνο πρόσωπο

ΠΑΡΑΡΤΗΜΑ

| Γραμμή | Μοντέλο | Χρώμα | 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 |
| M6 | 02,04,05 | AG,AS | 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 |
| 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 |
| 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 |
| 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 |

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| 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 | |
| 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 | |

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| 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 | 02,15,30M,32M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 458 | 02,15,30M,32M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 459 | 02,15,30M,32M | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| A12 | 500 | 01,02,15,01M,02M,15M,61,62 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 501 | 01,02,15,01M,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 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 508 | 01,02,15,63,64,65 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| | 509 | 01,02,15,63,64,65 | 4054514FRA-MIX-FULL-ADLG9 | Q02100203 |
| 510 | 01,02,15 | 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 | Q02100203 |
| | 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 | Q02100299 |
| | 03,04 | 501, 502 | 4054514FRA-OTH-FULL-ADLEQ | Q02100299 |