



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

Single Registration Number (SRN) **[SRN]**

Z pełną odpowiedzialnością oświadczamy, iż produkt

Nazwa produktu **oprawki do okularów / modele zobacz załącznik**

Basic UDI-DI **4054514FRA-MIX-FULL-ADLG9**

Nomenklatura **UMDNS Code (ECRI) 11-667, GMDN Code 32816, Q02100203**

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

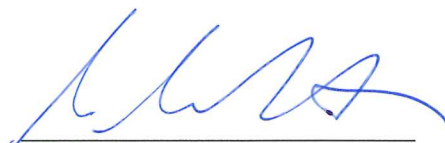
Rozporządzenie (WE) nr 1907/2006 w sprawie rejestracji, oceny, udzielania zezwoleń i stosowanych ograniczeń w zakresie chemikaliów (REACH)

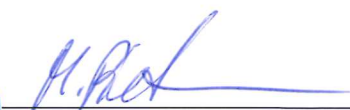
Zgodność z normą europejską EN ISO 12870

Prowadzimy procedurę systematycznego monitorowania produktu po wprowadzeniu go do obrotu.

Bad Liebenzell, 18.05.2021

Miejsce i data wydania

  
**Michael Fux**  
Kierownictwo

  
**Maria Pietsch**  
MDR osoba odpowiedzialna



ZAŁĄCZNIK

| Linia | Model               | Kolor  |
|-------|---------------------|--|
| M5    | 01,02,03,04,05      | AG,AS,GP,PP  |
| M9    | 01                  | AG,AS,GP,PP,RG,RGS   |
|       | 02                  | AG,AS,GP,PP,RG,SWS   |
|       | 03                  | AG,GP,PP,RG,RGS  |
|       | 04                  | AS,GP,PP,RG,SWS  |
|       | 05,06               | GP,PP,RG   |
| M10   | 01,02,03,04         | AG,AS,GP,PP,RG,RGS   |
|       | 05,06               | AG,AS,RGs  |
| M11   | 01,02,03,04         | AG,AS,RGs  |
| M12   | 01,02               | GP,GPs,PP,PPs,BR,BRs   |
| M13   | 01,02               | AG,AS,BL,PP,RG,SWs   |
|       | 03,04               | AG,AS,SWS  |
| M14   | 01,02,03,04         | AG,AS,RGS  |
| XXV   | 2501,2502,2503,2504 | GP,PP,GM   |
| C3    | 01, 02              | 03m GPS, 01m PPS, 04 matt RGS, 18m PPS, 02m RGS                                    |
| 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 |
|       | 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 |
|       | 230                 | 01,02,03   |
|       | 231                 | 01,02,03,16,17,18,40,41,42,01M,02M,03M,18M,26M                                     |
|       | 232                 | 01,02,03,05,06,18,40,41,42,01M,02M,03M,18M,26M                                     |
|       | 234                 | 01,02,03,05,06,14,15,16,17,18,36,37,38,40,41,42,55,56,01M,02M,03M,18M,26M          |
|       | 237                 | 01,02,03,  |
|       | 238                 | 01,02,03,18,01M,02M,03M,18M,26M  |
|       | 239                 | 01,02,03,40,41,42,01M,02M,03M  |
|       | 600                 | 01,02,03,36,37,38,53,54,55   |
|       | 601                 | 01,02,03,14,15,36,37,38,55,56,   |
|       | 602                 | 01,02,03,36,37,38  |
|       | 603                 | 01,02,03,36,37,38,53,54,55   |
|       | 604                 | 01,02,03,14,15,18  |
|       | 605                 | 01,02,03,01M,02M,03M   |
| A6    | 244                 | 01,02,03,04,18,33,01M,02M,03M,18M,26M  |
|       | 245                 | 01,02,01M,02M,18M,26M  |
|       | 246                 | 01,02,03,04,16,18,33,40,41,42,01M,02M,03M,18M,26M                                  |
|       | 249                 | 01,02,40,41,42,01M,02M,03M,  |
|       | 250                 | 01,02,03,18,33,40,41,42,01M,02M,03M,18M,26M  |
|       | 251                 | 01,02,03,01M,02M,03M,  |
|       | 252                 | 01,02,01M,02M,03M,   |



|     |     |                                     |
|-----|-----|-------------------------------------|
|     | 255 | 01,02,33,01M,02M,26M,               |
|     | 256 | 01,02,33,01M,02M,26M,               |
| A10 | 350 | 02,30,32,43,44,45,46                |
|     | 352 | 02,03,18,30,31,32,43,44,45,46       |
|     | 353 | 02,03,18,30,31,32,43,44,45,46       |
|     | 354 | 02,03,18,30,31,32                   |
|     | 355 | 02,03,18,30,31,32                   |
| A11 | 450 | 02,03,18,30,31,32,30M,31M,32M       |
|     | 451 | 02,03,14,15,18,30,31,32,30M,31M,32M |
|     | 452 | 02,03,14,15,18,30,31,32,30M,31M,32M |
|     | 453 | 02,03,14,15,18,30,31,32,30M,31M,32M |
|     | 454 | 01,02,03,30,31,32                   |
|     | 455 | 02,18,30,32,30M,32M                 |
|     | 456 | 01,02,03,30,31,32                   |
| A12 | 500 | 01,02,15,01M,02M,15M                |
|     | 501 | 01,02,15,01M,02M,15M                |
|     | 502 | 01,02,15,01M,02M,15M                |
|     | 503 | 01,02,15,01M,02M,15M                |
|     | 504 | 01,02,15,                           |
|     | 505 | 01,02,15,                           |
|     | 506 | 01,02,15,                           |
|     | 507 | 01,02,15,                           |
| A13 | 550 | 50,51,52                            |
|     | 551 | 50,51,52                            |
|     | 552 | 50,51,52                            |
|     | 553 | 50,51,52                            |