



isem tal produttur **Lunor AG**
Lunor Allee 1
75378 Bad Liebenzell
Germany

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

Aħna niddikjaraw taħt ir-responsabilita unika tagħna li l-prodott

Isem il-prodott **frejms ta' korrezzjoni / mudelli ara Anness**

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

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

klassi ta' riskju **klassi I – mhux sterili, l-ebda funzjoni ta' kejl**

Proċeduri ta' valutazzjoni tal-konformità **B'konformità ma' Artikolu 52 (7) għal tagħmir mediku**

ikkonforma mad-dispożizzjonijiet tal-leġislażzjonijiet li ġejjin:

Regolament (UE) 2017/745 tal-Parlament Ewropew u tal-Kunsill dwar apparati mediċi

REGOLAMENT (KE) NRU 1907/2006 dwar ir-registrazzjoni, il-valutazzjoni, l-awtorizzazzjoni u r-restrizzjoni ta' sustanzi kimiċi (REACH)


Jikkorrispondi mal-istandard Ewropew EN ISO 12870

Aħna nsostnu proċedura sistemika għal monitoraġġ tal-prodott wara li jitqiegħed fis-suq.

Bad Liebenzell, 18.05.2021

Post u data tal-ħruġ


Michael Fux
Maniġment


Maria Pietsch
MDR Persuna responsabbli

ANNEX

| Linja | Mudell | Kulur |
|-------|---------------------|--|
| 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 |