

gyártó neve **Lunor AG**
Lunor Allee 1
75378 Bad Liebenzell
Germany

Single Registration Number (SRN) **DE-MF-000022117**

Egyedüli felelősként kijelentjük, hogy a termék

terméknév név **szemüvegkeretek / modelleket lásd melléklet**

Basic UDI-DI **lásd a függelék**

Nómenklatúrája **GMDN Code 32816, EMDN Code lásd a függelék**

kockázati osztály **I. osztály - nem steril, nincs mérési funkció**

Megfelelőségértékelési eljárások **az 52. cikk (7) bekezdés szerint orvostechikai eszközre**

a következő jogi előírások rendelkezéseinek megfelel:

Az Európai Parlament és a Tanács (EU) 2017/745 rendelete az orvostechikai eszközökről

1907/2006/EK rendelete a vegyi anyagok regisztrálásáról, értékeléséről, engedélyezéséről és korlátozásáról (REACH))

az EN ISO 12870 Európai Normának megfelel


A termék forgalomba hozatala utáni ellenőrzésére szisztematikus eljárást tartunk fenn.

Bad Liebenzell, 25.09.2023

a kiállítás helye és dátuma



Michael Fux
ügyvezetés



Maria Pietsch
MDR felelős személy



MELLÉKLET

Vonal	Modell	Színes	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



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	



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
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