



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

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

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

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

Basic UDI-DI **ara Anness**

Nomenklatura **GMDN Code 32816, EMDN Code ara Anness**

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-legiżlazzjonijiet 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, 23.07.2024

Post u data tal-hruġ

Michael Fux
Maniġment

Maria Pietsch
MDR Persuna responsabbli

ANNEX

<i>Linja</i>	<i>Mudell</i>	<i>Kulur</i>	<i>Basic UDI-DI</i>	<i>EMDN Code</i>
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
	08	AG,AS	4054514FRA-MIX-FULL-ADLG9	Q02100203
M6	02,04,05,06	AG,AS,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,RGS,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	
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,56M	4054514FRA-MIX-FULL-ADLG9	Q02100203	
	607	01,02,15,41,55,56,01M,02M,15M, 26M,55M,56M	4054514FRA-MIX-FULL-ADLG9	Q02100203	
	610	01,02,15,41,55,56,01M,02M,15M, 26M,56M	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	02,15,30,32,30M,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	Q02100203
	501	01,02,15,61,62,63,64,65,66,67,68,70, 71,72, 01M,02M,15M	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	01,02,15,63,64,65,66,67,68,70,71,72	4054514FRA-MIX-FULL-ADLG9	Q02100203
	509	01,02,15,63,64,65,66,67,68,70,71,72	4054514FRA-MIX-FULL-ADLG9	Q02100203
	510	01,02,15,70,71,72	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	01,02,15,73,74,75	4054514FRA-MIX-FULL-ADLG9	Q02100203
	701	01,02,15,73,74,75	4054514FRA-MIX-FULL-ADLG9	Q02100203
	702	01,02,15,73,74,75	4054514FRA-MIX-FULL-ADLG9	Q02100203
	703	01,02,15,73,74,75	4054514FRA-MIX-FULL-ADLG9	Q02100203
	704	01,02,15,73,74,75	4054514FRA-MIX-FULL-ADLG9	Q02100203
	705	01,02,15,73,74,75	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