



ime proizvajalca

Lunor AG
Lunor Allee 1
75378 Bad Liebenzell
Germany

Single Registration Number (SRN)

DE-MF-000022117

Izjavljamo pod izključno odgovornostjo, da je izdelek

Ime izdelka

korekcijski okvirji / model glej Priloga

Basic UDI-DI

glej dodatek

Nomenklatura

GMDN Code 32816, EMDN Code glej dodatek

rizični razred

razred I – ni sterilno, brez merilne funkcije

Postopki ugotavljanja skladnosti

v skladu s sedmim odstavkom 52. člena za medicinske pripomočke

v skladu z določili naslednjih pravnih predpisov:

Uredba (EU) 2017/745 Evropskega parlamenta in Sveta z o medicinskih pripomočkih

Uredba (ES) št. 1907/2006 o registraciji, evalvaciji, avtorizaciji in omejevanju kemikalij (REACH)

v skladu z evropsko normo EN ISO 12870

Vzdržujemo sistematičen postopek za spremljanje izdelka po tem, ko ga damo na trg.

Bad Liebenzell, 23.07.2024

Kraj in datum izdaje

Michael Fux
Poslovno vodstvo

Maria Pietsch
MDR Odgovorni

PRILOGA

Linija	Model	Barva	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
	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