

Όνομα του κατασκευαστή

Lunor AG
Lunor Allee 1
75378 Bad Liebenzell
Germany

Single Registration Number (SRN)

DE-MF-000022117

Δηλώνουμε με αποκλειστική μας ευθύνη, ότι το προϊόν

Ονομασία προϊόντος

Γυαλιά οράσεως / Μοντέλα βλέπε παράρτημα

Basic UDI-DI

βλέπε παράρτημα

Ονοματολογία

GMDN Code 32816, EMDN Code βλέπε παράρτημα

Κατηγορία κινδύνου

Κατηγορία I – μη αποστειρωμένο, καμία λειτουργία μέτρησης

Διαδικασίες εκτίμησης της συμμόρφωσης

σύμφωνα με το άρθρο 52 (7) για ιατροτεχνολογικά προϊόντα

είναι σύμφωνο προς τις διατάξεις της ακόλουθης νομοθεσίας:

Κανονισμός (ΕΕ) 2017/745 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου για τα ιατροτεχνολογικά προϊόντα

ΚΑΝΟΝΙΣΜΟΣ (ΕΚ) αριθ 1907/2006 για την καταχώριση, την αξιολόγηση, την αδειοδότηση και τους περιορισμούς των χημικών προϊόντων (REACH)

Πληροί το ευρωπαϊκό πρότυπο EN ISO 12870

Εφαρμόζουμε μια συστηματική διαδικασία εποπτείας του προϊόντος μετά τη θέση του σε κυκλοφορία.

Bad Liebenzell, 09.01.2025

Τόπος και ημερομηνία έκδοσης



Michael Fux
Διεύθυνση επιχείρησης



Maria Pietsch
MDR Υπεύθυνο πρόσωπο



ΠΑΡΑΡΤΗΜΑ

Γραμμή	Μοντέλο	Χρώμα	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,RGS	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,BG,CBS,GG,GP,H S, NBS,PP,PPS,RG,RGS,RGS GN,SWS	4054514FRA-MIX-FULL-ADLG9	Q02100203
	02	AG,AG BR,AS,AS BL,GP,PP,RG,RGS, 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	Q02100203
	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	AG,AS,PPS BL,RGS,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,EBS,GOS,GPS,PPS,PRS,SWS	4054514FRA-MIX-FULL-ADLG9	Q02100203
	03,04	BBS,BLS,EBS,GPS,PPS,PRS		
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
	Rund M	AG,AS	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	AG,ASB,ASH,BR,PP	4054514FRA-MIX-FULL-ADLG9	Q02100203
Combi II A	23	ASB,DG,PP,PPH	4054514FRA-MIX-FULL-ADLG9	Q02100203
	24,25	AS,AG,ASB,DG,PP,PPH	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,85,85M	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,56M85, 85M	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,85,85M	4054514FRA-MIX-FULL-ADLG9	Q02100203
	237	01,02,03,40,41,02M,03M	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	01,02,03,14,15,36,37,38,55,56,85	4054514FRA-MIX-FULL-ADLG9	Q02100203
	602	01,02,03,36,37,38,53,54,55	4054514FRA-MIX-FULL-ADLG9	Q02100203
	603	01,02,03,36,37,38,40,41,53,54,55,85	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,41M,56M85M	4054514FRA-MIX-FULL-ADLG9	Q02100203
	607	01,02,15,41,55,56,01M,02M,15M, 26M,55M,56M	4054514FRA-MIX-FULL-ADLG9	Q02100203
	610	01,02,15,41,55,56,85,01M,02M,15M, 26M,56M,85M	4054514FRA-MIX-FULL-ADLG9	Q02100203
	612	01,02,15,40,41,85	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	01,02,03,14,15,18,30,31,32,57,58,59, 82,83,84,30M,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	01,02,15,30,32,82,83,84,30M,32M	4054514FRA-MIX-FULL-ADLG9	Q02100203
	458	02,15,30M,32M	4054514FRA-MIX-FULL-ADLG9	Q02100203
	459	01,02,15,30,32,30M,32M,76M,77M, 78M	4054514FRA-MIX-FULL-ADLG9	Q02100203
	460	01,02,15,76M,77M,78M	4054514FRA-MIX-FULL-ADLG9	Q02100203
	461	01,02,15,79,80,81	4054514FRA-MIX-FULL-ADLG9	Q02100203
	462	01,02,15,79,80,81	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