



ime proizvajalca

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

Single Registration Number (SRN)

[SRN]

Izjavljamo pod izključno odgovornostjo, da je izdelek

Ime izdelka

korekcijski okvirji / model glej Priloga

Basic UDI-DI

4054514FRA-MIX-FULL-ADLG9

Nomenklatura

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

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, 18.05.2021

Kraj in datum izdaje


Michael Fux
Poslovno vodstvo


Maria Pietsch
MDR Odgovorni



PRILOGA

Linija	Model	Barva
M5	01,02,03,04,05	AG,AS,GP,PP
M9	01 02 03 04 05,06	AG,AS,GP,PP,RG,RGS AG,AS,GP,PP,RG,SWS AG,GP,PP,RG,RGS AS,GP,PP,RG,SWS GP,PP,RG
M10	01,02,03,04 05,06	AG,AS,GP,PP,RG,RGS AG,AS,RGs
M11	01,02,03,04	AG,AS,RGs
M12	01,02	GP,GPs,PP,PPs,BR,BRs
M13	01,02 03,04	AG,AS,BL,PP,RG,SWs 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	215 226 230 231 232 234 237 238 239 600 601 602 603 604 605	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 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 01,02,03 01,02,03,16,17,18,40,41,42,01M,02M,03M,18M,26M 01,02,03,05,06,18,40,41,42,01M,02M,03M,18M,26M 01,02,03,05,06,14,15,16,17,18,36,37,38,40,41,42,55,56,01M,02M,03M,18M,26M 01,02,03, 01,02,03,18,01M,02M,03M,18M,26M 01,02,03,40,41,42,01M,02M,03M 01,02,03,36,37,38,53,54,55 01,02,03,14,15,36,37,38,55,56, 01,02,03,36,37,38 01,02,03,36,37,38,53,54,55 01,02,03,14,15,18 01,02,03,01M,02M,03M
A6	244 245 246 249 250 251 252	01,02,03,04,18,33,01M,02M,03M,18M,26M 01,02,01M,02M,18M,26M 01,02,03,04,16,18,33,40,41,42,01M,02M,03M,18M,26M 01,02,40,41,42,01M,02M,03M, 01,02,03,18,33,40,41,42,01M,02M,03M,18M,26M 01,02,03,01M,02M,03M, 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