

*La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE*

Către: Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. din

Solicitantul Medica Sens SRL, cu sediul Mun. Chisinau, str. Calarași 66, tel./fax: 078737324, e-mail: office@medicasens.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a dispozitivelor medicale din Anexa nr. 3:

Nr.	Numărul de catalog (referință)*	Denumire generică	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	-	Catheter	-	5E-9-100P	35053
2	-	Catheter	-	5E-9-100D	35053
3	-	Catheter	-	9E-12-100A	35053
4	-	Esophageal catheter 4 helicoidal channels at 5 cm	-	5E-12-100	35053
5	-	Esophageal catheter 4 helicoidal channels at 5 cm	-	5E-12-100H	35053
6	-	Esophageal catheter 8 channels, 4 radials at 0 and 4 helicoidal at 5 cm	-	9E-12-100	35053
7	-	Esophageal catheter 8 channels, 4 at 1 cm from 0 and 4 at 5 cm	-	9E-12-100L	35053
8	-	Esophageal catheter 8 channels, 4 radials and 4 helicoidal at 5 cm	-	9E-12-100H	35053
9	-	Esophageal catheter for HRM with 20 ports	-	21E-14-100	35053
10	-	Esophageal catheter for HRM with 24 ports	-	25HE-14-140A	35053
11	-	Catheter	-	5R-9-100CB	17745
12	-	Catheter	-	5R-12-100CB	17745
13	-	Catheter	-	5R-12-100VB	17745
14	-	Catheter	-	9R-12-100CB	17745
15	-	Catheter	-	9R-12-100V	17745
16	-	Catheter	-	9R-12-100VB	17745
17	-	Catheter	-	5R-12-100KB	17745
18	-	Catheter	-	9G-12-130C	17745
19	-	9-ways catheter for anorectal manometry	-	ISCHIA	17745
20	-	Anorectal manometry catheter 4 radial channels at 0 cm and balloon at -1 cm	-	5R-12-100	17745

21	-	Anorectal manometry catheter 4 helicoidal channels at 1 cm and balloon at –1 cm	-	5R-12-100L	17745
22	-	Anorectal manometry catheter 4 helicoidal channels at 1 cm and balloon at –3 cm	-	5R-12-100L3	17745
23	-	Anorectal manometry catheter 4 helicoidal channels at 1 cm from the balloon	-	5R-12-100LH	17745
24	-	Anorectal manometry catheter 4 radial channels at 0 cm and balloon at –3 cm	-	5R-12-100VB3	17745
25	-	Anorectal manometry catheter 4 radial channels at 0 cm and balloon at –3 cm	-	5R-12-100VB3H	17745
26	-	Anorectal manometry catheter with 4 helicoidal channels at 0.5 cm, 4 radial and balloon at –1 cm	-	9R-12-100	17745
27	-	Anorectal manometry catheter 8 helicoidally channels at 1 cm at 0 cm and balloon at –2.5 cm	-	9R-12-100KB	17745
28	-	Anorectal manometry catheter with 8 helicoidal channels at 0.5 cm and balloon at –1 cm	-	9R-12-100L	17745
29	-	Anorectal manometry catheter 8 radial channels at 0 cm and balloon at –1 cm	-	9R-12-100VB1	17745
30	-	Anorectal manometry catheter 8 radial channels at 0 cm and balloon at –3 cm	-	9R-12-100VB3	17745
31	-	Anorectal manometry catheter 8 radial channels at 0 cm and balloon at –5 cm	-	9R-12-100VB5	17745
32	-	Anorectal manometry catheter with radial 8 channels with balloon	-	9R-12-100VB1H	17745
33	-	9-ways Anorectal Manometry Catheter with latex-free balloon, 12 Fr	-	9R-12-100SR	17745
34	-	9-ways colon Manometry Catheter	-	9C-12-130A	17745
35	-	Anorectal manometry catheter with radial 12 channels with balloon	-	13R-14-100	17745
36	-	Catheter	-	2CYS-9	44675
37	-	Catheter	-	2omni-9	44675
38	-	Catheter	-	2CYS-6 PIG	44675
39	-	Catheter	-	3omni-9	44675
40	-	Catheter	-	2CYS-9E	44675
41	-	Catheter	-	3omni-9E	44675
42	-	Catheter	-	1TIE-9	44675
43	-	Catheter	-	2omni-9R	44675
44	-	Catheter	-	2omni-8P	44675
45	-	Catheter	-	3omni-8P	44675
46	-	Catheter	-	3omni-8UP	44675
47	-	Catheter	-	2omni-8pH	44675
48	-	Set of a 2-way catheter, 6 Fr and a 1-way catheter, 5 Fr(2CYS-6LE + 1AR-5TI)	-	CPS-D-6MX	44675
49	-	Set of a 2-way catheter, 6 Fr and 9 Fr a 1-way catheter, 5 Fr(2CYS-6LE + 2AR-9TI)	-	CPS-D-6MX9	44675

50	-	Set of a 2-ways catheter, 8 Fr and a 1-way catheter, 5 Fr(2CYS-8PE + 1AR-5TI)	-	CPS-D-8MX	44675
51	-	Set of a 2-ways catheter, 8 Fr and 12 Fr (2CYS-8LE + 2AR-12TE)	-	CPS-D-8MX12	44675
52	-	Set of a 2-ways catheter, 6 Fr and 12 Fr (2CYS-6LE + 2AR-12TE)	-	CPS-D-12MX	44675
53	-	Set of three catheters, 1 way (1BF-8P + 1PF-5PE + 1AR-5TI)	-	CPS-S-MX	44675
54	-	Catheter	-	2CYS-6	44675
55	-	Catheter	-	2CYS-6L	44675
56	-	Catheter	-	2omni-6	44675
57	-	Catheter	-	1PF-4	44675
58	-	Catheter	-	1BF-9	44675
59	-	2-way Mercier catheter for pressure flow study	-	2PF-6M	44675
60	-	Catheter	-	1PF-4L PIG	44675
61	-	Catheter	-	1PF-4E	44675
62	-	Catheter	-	2CYS-6LE	44675
63	-	Catheter	-	2CYS-6P	44675
64	-	Catheter	-	2omni-6NP	44675
65	-	Catheter	-	2CYS-8P	44675
66	-	Set PF	-	SET PF	44675
67	-	2-ways catheter in PVC, 8Fr	-	2CYS-8PE	44675
68	-	2-way catheter for cystometry – PFS in PVC, soft, 8 Fr with blue line	-	2CYS-8PES	44675
69	-	1-way catheter for bladder filling in PVC, 8 Fr	-	1BF-8P	44675
70	-	1-way catheter for bladder pressure in PVC 1.8 m long, 5 Fr	-	1PF-5PE	44675
71	-	Double way catheter with Coude tip in PVC 8 Fr diameter	-	2TIE-8P	44675
72	-	Catheter	-	2PP-9L	44675
73	-	Catheter	-	5PPV-9	44675
74	-	Catheter	-	2omni-6N	44675
75	-	Catheter	-	1AR-12	44675
76	-	Catheter	-	1AR-12SC	44675
77	-	Catheter	-	2AR-9	44675
78	-	Catheter	-	2AR-12L	44675
79	-	Catheter	-	2AR-12SM	44675
80	-	Catheter	-	2AR-12SL	44675
81	-	Catheter	-	2AR-12MX	44675
82	-	Catheter	-	2AR-9T	44675
83	-	Catheter	-	2AR-9TE	44675
84	-	Catheter	-	2AR-12T	44675
85	-	Catheter	-	1AR-5T	44675
86	-	Catheter	-	2AR-9E	44675

87	-	Catheter	-	2AR-9TS	44675
88	-	Catheter	-	2AR-12TS	44675
89	-	Catheter	-	2AR-12TE	44675
90	-	Catheter	-	1AR-5TC	44675
91	-	Catheter	-	2AR-9TM	44675
92	-	Catheter 7x20 mm	-	1AR-5I	44675
93	-	1-way Rectal catheter, 5 Fr with line, balloon and introducer	-	1AR-5TI	44675
94	-	1-way Rectal catheter, 5 Fr with line, balloon with slit and new introducer	-	1AR-5IS	44675
95	-	CAV SET line	-	CAV SET	44675
96	-	Abdominal catheter with 1 balloon	-	1RB-12B1	44675
97	-	Abdominal catheter with 2 balloons	-	2RB-12B2	44675
98	-	3-way stop-cock with luer lock	-	SC3	44675
99	-	Very-Low compliance Extension line with 3-way stop-cock	-	EXT-180/SC3	44675
100	-	Very-Low compliance Extension line	-	EXT-180	44675
101	-	Peristaltic Pump Set	-	QUICK SBC	35833
102	-	Subpump Segm. PharMed for peristaltic pump Pico QUICK	-	QUICK SP	35833
103	-	Cystomanometry line	-	L-CYS	44675
104	-	Male Cone Adapter with female luer lock	-	ADA-MF	44675
105	-	2-way stop-cock with luer lock	-	SC2	44675
106	-	Infusion set for Peristaltic pump	-	WTP	35833
107	-	Quadruple Capillary Infusion set	-	QCI	44675
108	-	Infusion Line Set with pump segment PVC and capillary for UPP	-	WTP/UP SET	35833
109	-	Single Capillary Infusion set	-	SCI Set	44675
110	-	Blue Extension line	-	EXT-180B	44675
111	-	Red Extension line	-	EXT-180R	44675
112	-	Yellow Extension line	-	EXT-180Y	44675
113	-	Extension line Ø 3x4 mm	-	E34-180	44675
114	-	Non return valve with FLL and MLL	-	NRV	35833
115	-	Pump tubing set LT 3011	-	WTP-LT2	35833
116	-	Extension line, 150 cm, transparent with Blue connectors	-	EXT-150TB	44675
117	-	Extension line, 150 cm, transparent with Red connectors	-	EXT-150TR	44675
118	-	Extension line, 150 cm, transparent with Yellow connectors	-	EXT-150TY	44675
119	-	Luer Lock Maschio	-	M90349	35833
120	-	Set for the filling of the pressure lines	-	SF3	44675

* - dacă este aplicabil.

Se anexează următoarele acte:

1. CERTIFICAT CE

2. DECLARATIE DE CONFORMITATE

3. ACORD AUTORIZATIE DE LA PRODUCATOR , Medica S.p.A. , Italia

Data 30.10.2024

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	