

**MEDIPLUS (INDIA) LIMITED****MIL/FSN/02**

Urgent Field Safety Notice**Commercial name of the affected product:** Various Brand of Peripheral Venous Catheter**Type of action:** Recall of Various Brand of Peripheral Venous Catheter.

Date: 07-08-2018**Attention:** Health Care Professionals.**Details on affected device:**

Nomenclature system:	UMDNS (ECRI)
Nomenclature code:	10727
Type of device:	Catheter, intravascular, peripheral
Model name:	Various Brand of Peripheral Venous Catheter

Details of affected batch no: As per the attached annexure-1 (dispatch details to Socime)**Description of the problem:**

Mediplus (India) Limited has received information regarding several types of problems experienced by the users when using the various Brands of Peripheral Venous Catheter. Mediplus (India) Limited has decided to recall of all batches.

Consequences of the Problem:

1) Phlebitis, oedema, pain, discomfort, lesion at the site of puncture, serum or blood leakage, ruptured veins, catheter separating from the catheter hub;

2) Several time vein rupture.

Description and justification of the action:

Considering the above mentioned problems, and after discussing this issue with Infarmed, we have decided to recall all brands of Peripheral Venous Catheters.

Advise on action to be taken by the user:

This is inform that all Healthcare Professional/Users" must 'Immediately Stop' **using the device** & learn that the use of the device has to be suspended immediately and that the concerned products will have to be collected. The healthcare professional should identify and quarantine the devices affected by this recall. The distributor Socime Medical will contact you in order to collect the remaining devices."

Mediplus (India) Limited

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**MEDIPLUS (INDIA) LIMITED****Contact Details:****SOCIME MEDICAL****Mr. Luis Ferreira Godinho**

R. Jose Fontana, 1-1º Esq. 2770-101 Paco D'Arcos

Lisboa, Portugal

Phone: +35 1963017045, **Fax:** +35 1214716170**E-mail:** luis.godinho@socime-medical.com

All recall product will be sent back to Mediplus (India) Limited.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

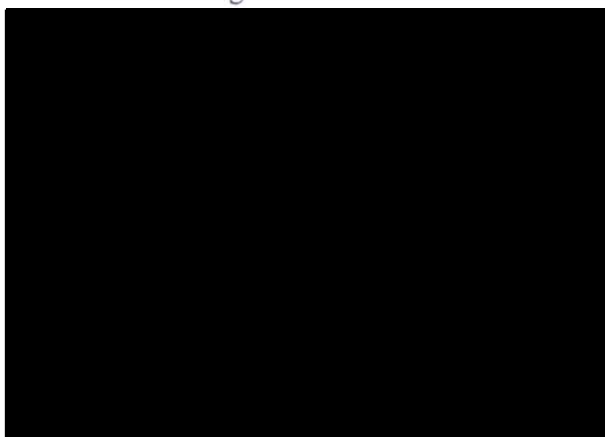
Please transfer this notice to other organization on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Name: Mr. Sharad Mittal
Organization: MEDIPLUS (INDIA) LIMITED
Address: 1261-1262, M.I.E., Part-B
Bahadurgarh, Haryana -124507
INDIA
Contact details: M: + 919811170505
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The undersign confirms that this notice has been notified the appropriate Regulatory Agency.



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MEDIPLUS (INDIA) LIMITED

Affected Batches of Pluscan Alpha

Sr. No.	Reference No	Gauge	B. No.	Mfg. Date	Exp. Date
1	Samples	14G	40213/095	2014-06	2019-05
2		16G	40214/095	2014-06	2019-05
3		18G	40216/095	2014-06	2019-05
4		20G	40215/095	2014-06	2019-05
5		22G	40217/095	2014-06	2019-05
6		24G	40230/095	2014-06	2019-05
7	1451421610	14G	41099/440	2015-01	2019-12
8	1451621610	16G	41100/440	2015-01	2019-12
9	1451821610	18G	41101/440	2015-01	2019-12
10	1452021610	20G	41102/448	2015-01	2019-12
11	1452221610	22G	41103/440	2015-01	2019-12
12	1452421610	24G	41104/440	2015-01	2019-12
13	1041621618	16G	41316/520	2015-03	2020-02
14	1041821618	18G	41317/518	2015-03	2020-02
15	1042021618	20G	41318/518	2015-03	2020-02
16	1042221618	22G	41376/520	2015-03	2020-02
17	1042421618	24G	41319/520	2015-03	2020-02
18	14X1621618	16G	50158/075	2015-06	2020-05
19	14X1821618	18G	50159/072	2015-06	2020-05
20	14X2021618	20G	50160/072	2015-06	2020-05
21	14X2221618	22G	50161/075	2015-06	2020-05
22	14X2421618	24G	50162/075	2015-06	2020-05
23	14X2621618	26G	50163/075	2015-06	2020-05
24	14X1421618	14G	50440/190	2015-08	2020-07
25	14X1621618	16G	50381/190	2015-08	2020-07
26	14X1821618	18G	50382/190	2015-08	2020-07
27	14X2021618	20G	50383/185	2015-08	2020-07
28	14X2221618	22G	50441/190	2015-08	2020-07
29	14X2421618	24G	50442/190	2015-08	2020-07
30	14X2621618	26G	50443/190	2015-08	2020-07
31	14X1421618	14G	50862/360	2015-12	2020-11
32	14X2421618	24G	50863/360	2015-12	2020-11
33	14X2621618	26G	50864/360	2015-12	2020-11
34	14X1621618	16G	50991/437	2016-02	2021-01
35	14X1821618	18G	50949/437	2016-02	2021-01
36	14X2021618	20G	50989/437	2016-02	2021-01
37	14X2221618	22G	50950/437	2016-02	2021-01
38	14X2421618	24G	50951/437	2016-02	2021-01

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Affected Batches of Pluscan Alpha

Sr. No.	Reference No	Gauge	B. No.	Mfg. Date	Exp. Date
39	14X1421618	14G	51119/490	2016-03	2021-02
40	14X1621618	16G	51120/490	2016-03	2021-02
41	14X1421618	14G	60293/136	2016-07	2021-06
42	14X1821618	18G	60294/136	2016-07	2021-06
43	14X2021618	20G	60295/136	2016-07	2021-06
44	14X2221618	22G	60296/136	2016-07	2021-06
45	14X2421618	24G	60297/136	2016-07	2021-06
46	14X1421618	14G	60344/153	2016-07	2021-06
47	14X1621618	16G	60342/153	2016-07	2021-06
48	14X1821618	18G	60343/153	2016-07	2021-06
49	14X2021618	20G	60339/153	2016-07	2021-06
50	14X2221618	22G	60340/151	2016-07	2021-06
51	14X2421618	24G	60341/151	2016-07	2021-06
52	14X2621618	26G	60578/234	2016-09	2021-08
53	14X1421618	14G	60456/228	2016-09	2021-08
54	14X1821618	18G	60468/264	2016-09	2021-08
55	14X2021618	20G	60452/226	2016-09	2021-08
56	14X2221618	22G	60454/228	2016-09	2021-08
57	14X2421618	24G	60455/228	2016-09	2021-08
58	14X2621618	26G	70110/033	2017-05	2022-04
59	14X1421618	14G	70510/191	2017-08	2022-07
60	14X1621618	16G	70511/192	2017-08	2022-07
61	14X1821618	18G	70509/191	2017-08	2022-07
62	14X2021618	20G	70506/191	2017-08	2022-07
63	14X2221618	22G	70507/191	2017-08	2022-07
64	14X2421618	24G	70508/191	2017-08	2022-07
65	14X2621618	26G	70512/192	2017-08	2022-07
66	14X1821618	18G	70784/314	2017-11	2022-10
67	14X2021618	20G	70705/314	2017-11	2022-10
68	14X2221618	22G	70785/314	2017-11	2022-10
69	14X1821618	18G	71146/476	2018-02	2023-01
70	14X2021618	20G	71149/477	2018-02	2023-01
71	14X2221618	22G	71136/476	2018-02	2023-01
72	14X2621618	26G	71150/472	2018-02	2023-01

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Affected Batches of Pluscan

Sr. No.	Reference No	Gauge	B. No.	Mfg. Date	Exp. Date
1	Samples	16G	40207/095	2014-06	2019-05
2		18G	40234/095	2014-06	2019-05
3		20G	40235/095	2014-06	2019-05
4		22G	40236/095	2014-06	2019-05
5		24G	40237/095	2014-06	2019-05
6	1031421610	14G	41093/438	2015-01	2019-12
7	1031621610	16G	41094/440	2015-01	2019-12
8	1031821610	18G	41095/440	2015-01	2019-12
9	1032021610	20G	41096/440	2015-01	2019-12
10	1032221610	22G	41097/438	2015-01	2019-12
11	1032421610	24G	41098/440	2015-01	2019-12
12	1031421610	14G	41311/518	2015-03	2020-02
13	1031621610	16G	41312/510	2015-03	2020-02
14	1031821610	18G	41313/510	2015-03	2020-02
15	1032021610	20G	41314/492	2015-02	2020-01
16	1032221610	22G	41375/520	2015-03	2020-02
17	1032421610	24G	41315/518	2015-03	2020-02
18	1031421610	14G	50164/133	2015-07	2020-06
19	1031621610	16G	50165/133	2015-07	2020-06
20	1031821610	18G	50166/135	2015-07	2020-06
21	1032021610	20G	50167/135	2015-07	2020-06
22	1032221610	22G	50168/133	2015-07	2020-06
23	1032421610	24G	50169/135	2015-07	2020-06
24	1031421610	14G	50437/190	2015-08	2020-07
25	1031621610	16G	50378/185	2015-08	2020-07
26	1031821610	18G	50379/185	2015-08	2020-07
27	1032021610	20G	50380/174	2015-07	2020-06
28	1032221610	22G	50438/179	2015-08	2020-07
29	1032421610	24G	50439/190	2015-08	2020-07
30	1032621610	26G	50864/360	2015-12	2020-11
31	1032021610	20G	50992/437	2016-02	2020-01
32	1032221610	22G	50953/437	2016-02	2020-01
33	1031821610	18G	50952/437	2016-02	2021-01
34	1032021610	20G	50992/437	2016-02	2021-01
35	1032221610	24G	50954/437	2016-02	2021-01
36	1031821610	18G	70307/111	2017-07	2022-06
37	1032021610	20G	70323/117	2017-07	2022-06
38	1032221610	22G	70317/117	2017-07	2022-06
39	1032621610	26G	70325/117	2017-07	2022-06
40	1031421610	14G	70530/192	2017-08	2022-07
41	1031621610	16G	70531/192	2017-08	2022-07
42	1032421610	24G	70532/192	2017-08	2022-07
43	1031821610	18G	71151/477	2018-03	2023-02
44	1032021610	20G	71152/477	2018-03	2023-02

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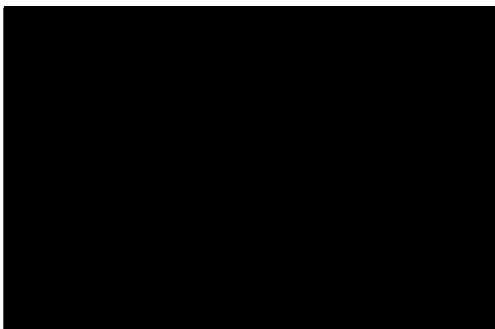
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**MEDIPLUS (INDIA) LIMITED****Affected Batches of Plusflon**

Sr. No.	Reference No	Gauge	B. No.	Mfg. Date	Exp. Date
1	Samples	18G	40247/095	2014-06	2019-05
2		20G	40248/095	2014-06	2019-05
3		22G	40240/095	2014-06	2019-05
4	1011421610	14G	41087/438	2015-01	2019-12
5	1011621610	16G	41088/440	2015-01	2019-12
6	1011821610	18G	41089/438	2015-01	2019-12
7	10112021610	20G	41090/438	2015-01	2019-12
8	10112221610	22G	41091/438	2015-01	2019-12
9	10112421610	24G	41092/440	2015-01	2019-12
10	1011421610	14G	41307/520	2015-03	2020-02
11	1011621610	16G	41308/510	2015-03	2020-02
12	1011821610	18G	41309/510	2015-03	2020-02
13	10112021610	20G	41310/518	2015-03	2020-02
14	10112221610	22G	41374/520	2015-03	2020-02
15	1011421610	14G	50135/075	2015-06	2020-05
16	1011621610	16G	50136/075	2015-06	2020-05
17	1011821610	18G	50137/075	2015-06	2020-05
18	10112021610	20G	50138/075	2015-06	2020-05
19	10112221610	22G	50139/075	2015-06	2020-05



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**MEDIPLUS (INDIA) LIMITED****Affected Batches of Pluscan Alpha Safe**

Sr. No.	Reference No	Gauge	B. No.	Mfg. Date	Exp. Date
1	Samples	14G	40269/095	2014-06	2019-05
2		16G	40270/095	2014-06	2019-05
3		18G	40223/095	2014-06	2019-05
4		20G	40226/095	2014-06	2019-05
5		22G	40251/095	2014-06	2019-05
6		24G	40252/095	2014-06	2019-05
7	932142261C	14G	41073/448	2015-01	2019-12
8	932162261C	16G	41074/448	2015-01	2019-12
9	932182261C	18G	41105/448	2015-01	2019-12
10	932202261C	20G	41106/448	2015-01	2019-12
11	932222261C	22G	41107/448	2015-01	2019-12
12	932242261C	24G	41108/448	2015-01	2019-12
13	932202261C	20G	50170/100	2015-06	2020-05
14	932142261C	14G	50858/360	2015-12	2020-11
15	932162261C	16G	50859/360	2015-12	2020-11
16	932182261C	18G	50860/360	2015-12	2020-11
17	932202261C	20G	50793/360	2015-12	2020-11
18	932222261C	22G	50827/360	2015-12	2020-11
19	932242261C	24G	50861/360	2015-12	2020-11
20	932182261C	18G	50995/441	2016-02	2021-01
21	932202261C	20G	50996/441	2016-02	2021-01
22	932222261C	22G	50966/416	2016-01	2020-12
23	932142261C	14G	50993/441	2016-02	2021-01
24	932162261C	16G	50994/441	2016-02	2021-01
25	932202261C	20G	50996/441	2016-02	2021-01
26	932242261C	24G	50973/441	2016-02	2021-01
27	932182261C	18G	51118/504	2016-03	2021-02
28	932202261C	20G	51124/504	2016-03	2021-02
29	932222261C	22G	51149/514	2016-03	2021-02
30	932182261C	18G	60311/136	2016-07	2021-06
31	932202261C	20G	60316/136	2016-07	2021-06
32	932222261C	22G	51149/514A	2016-03	2021-02
33	932242261C	24G	60312/136	2016-07	2021-06
34	932222261C	22G	60471/234	2016-09	2021-08
35	932242261C	24G	60472/234	2016-09	2021-08
36	932182261C	18G	60469/264	2016-09	2021-08
37	932202261C	20G	60470/248	2016-09	2021-08
38	932202261C	20G	60577/264	2016-09	2021-08
39	932222261C	22G	60471/234	2016-09	2021-08
40	932222261C	22G	60556/248	2016-09	2021-08
41	932182261C	18G	60907/395	2016-12	2021-11
42	932202261C	20G	60896/395	2016-12	2021-11
43	932202261C	20G	60908/395	2016-12	2021-11
44	932222261C	22G	60909/395	2016-12	2021-11
45	932242261C	24G	60910/395	2016-12	2021-11

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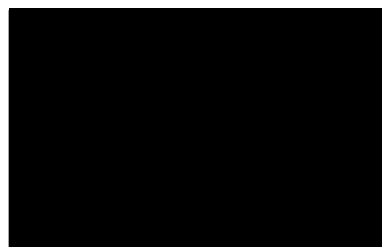
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**MEDIPLUS (INDIA) LIMITED****Affected Batches of Plusflon Safe**

Sr. No.	Reference No	Gauge	B. No.	Mfg. Date	Exp. Date
1	Samples	14G	40253/095	2014-06	2019-05
2		16G	40254/095	2014-06	2019-05
3		18G	40220/095	2014-06	2019-05
4		20G	40221/095	2014-06	2019-05
5		22G	40260/095	2014-06	2019-05
6	935142261C	14G	41109/448	2015-01	2019-12
7	935162261C	16G	41110/448	2015-01	2019-12
8	935182261C	18G	41111/448	2015-01	2019-12
9	935202261C	20G	41112/448	2015-01	2019-12
10	935222261C	22G	41113/448	2015-01	2019-12
11	935242261C	24G	41114/448	2015-01	2019-12

Affected Batches of Plusclip Alpha Safe

Sr. No.	Reference No	Gauge	B. No.	Mfg. Date	Exp. Date
1	923182161E	18G	50705/320	2015-11	2020-10
2	923202161E	20G	50706/320	2015-11	2020-10
3	923142161E	14G	51000/441	2016-02	2021-01
4	923162161E	16G	50932/399	2016-01	2020-12
5	923182161E	18G	50904/399	2016-01	2020-12
6	923202161E	20G	50883/382	2015-12	2020-11
7	923222161E	22G	50905/385	2015-12	2020-11
8	923242161E	24G	50933/399	2016-01	2020-12
9	923182161E	18G	60922/395	2016-12	2021-11



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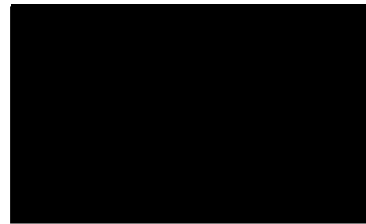
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**MEDIPLUS (INDIA) LIMITED****Affected Batches of Plusclip**

Sr. No.	Reference No	Gauge	B. No.	Mfg. Date	Exp. Date
1	965182161E	18G	50707/320	2015-11	2020-10
2	965202161E	20G	50708/320	2015-11	2020-10
1	965142161E	14G	50955/441	2016-02	2021-01
2	965162161E	16G	50956/441	2016-02	2021-01
3	965182161E	18G	50957/433	2016-02	2021-01
4	965202161E	20G	50997/433	2016-02	2021-01
5	965222161E	22G	50998/437	2016-02	2021-01
6	965242161E	24G	50999/441	2016-02	2021-01

Affected Batches of Plusclip Safe

Sr. No.	Reference No	Gauge	B. No.	Mfg. Date	Exp. Date
1	921182161E	18G	50487/193	2015-08	2020-07
2	921202161E	20G	50488/193	2015-08	2020-07
3	921142161E	14G	50936/408	2016-02	2021-01
4	921162161E	16G	50937/408	2016-02	2021-01
5	921182161E	18G	50938/408	2016-02	2021-01
6	921202161E	20G	50939/408	2016-02	2021-01
7	921242161E	24G	50940/408	2016-01	2020-12
8	921222161E	22G	50947/408	2016-02	2021-01
9	921202161E	20G	60866/366	2016-12	2021-11
10	921202161E	22G	60948/397	2016-12	2021-11
11	921222161E	22G	60967/421	2017-01	2021-12



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