



DEVICE DETAILS

NAME OF DEVICE	CORONARY DILATATION CATHETER-NON-COMPLIANT
ESTABLISHMENT NAME	MITSU SCIENTIFIC SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GD1219420-41771
BRAND NAME	NC-TADPOLE
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Coronary dilatation catheter provided by Lepu medical has two types, semi-compliant balloon dilation catheter and non-compliant balloon dilation catheter. NC Tadpole™ is non-compliant balloon dilation catheter. The noncompliant balloon material allows higher dilation pressure than semi-compliant material. According to EN ISO 10555-1:2013, Coronary Dilatation Catheter is coated with hydrophilic coating which is activated when wet. That's to say it is hydrophilic intravascular catheter.
DEVICE INTENDED PURPOSE	Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion; -Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction;
VALIDITY DATE OF REGISTRATION	02/04/2020 - 01/04/2025

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	NC Tadpole™ Coronary Dilatation Catheter	LPNRX15006
2	NC Tadpole™ Coronary Dilatation Catheter	LPNRX20006
3	NC Tadpole™ Coronary Dilatation Catheter	LPNRX22006
4	NC Tadpole™ Coronary Dilatation Catheter	LPNRX25006
5	NC Tadpole™ Coronary Dilatation Catheter	LPNRX27006
6	NC Tadpole™ Coronary Dilatation Catheter	LPNRX30006
7	NC Tadpole™ Coronary Dilatation Catheter	LPNRX32006
8	NC Tadpole™ Coronary Dilatation Catheter	LPNRX35006
9	NC Tadpole™ Coronary Dilatation Catheter	LPNRX37006

NO	NAME OF DEVICE	IDENTIFIER
10	NC Tadpole™ Coronary Dilatation Catheter	LPNRX40006
11	NC Tadpole™ Coronary Dilatation Catheter	LPNRX45006
12	NC Tadpole™ Coronary Dilatation Catheter	LPNRX50006
13	NC Tadpole™ Coronary Dilatation Catheter	LPNRX15008
14	NC Tadpole™ Coronary Dilatation Catheter	LPNRX20008
15	NC Tadpole™ Coronary Dilatation Catheter	LPNRX22008
16	NC Tadpole™ Coronary Dilatation Catheter	LPNRX25008
17	NC Tadpole™ Coronary Dilatation Catheter	LPNRX27008
18	NC Tadpole™ Coronary Dilatation Catheter	LPNRX30008
19	NC Tadpole™ Coronary Dilatation Catheter	LPNRX32008
20	NC Tadpole™ Coronary Dilatation Catheter	LPNRX35008
21	NC Tadpole™ Coronary Dilatation Catheter	LPNRX37008
22	NC Tadpole™ Coronary Dilatation Catheter	LPNRX40008
23	NC Tadpole™ Coronary Dilatation Catheter	LPNRX45008
24	NC Tadpole™ Coronary Dilatation Catheter	LPNRX50008
25	NC Tadpole™ Coronary Dilatation Catheter	LPNRX15010
26	NC Tadpole™ Coronary Dilatation Catheter	LPNRX20010
27	NC Tadpole™ Coronary Dilatation Catheter	LPNRX22010
28	NC Tadpole™ Coronary Dilatation Catheter	LPNRX25010
29	NC Tadpole™ Coronary Dilatation Catheter	LPNRX27010
30	NC Tadpole™ Coronary Dilatation Catheter	LPNRX30010
31	NC Tadpole™ Coronary Dilatation Catheter	LPNRX32010
32	NC Tadpole™ Coronary Dilatation Catheter	LPNRX35010
33	NC Tadpole™ Coronary Dilatation Catheter	LPNRX37010
34	NC Tadpole™ Coronary Dilatation Catheter	LPNRX40010
35	NC Tadpole™ Coronary Dilatation Catheter	LPNRX45010

NO	NAME OF DEVICE	IDENTIFIER
36	NC Tadpole™ Coronary Dilatation Catheter	LPNRX50010
37	NC Tadpole™ Coronary Dilatation Catheter	LPNRX15012
38	NC Tadpole™ Coronary Dilatation Catheter	LPNRX20012
39	NC Tadpole™ Coronary Dilatation Catheter	LPNRX22012
40	NC Tadpole™ Coronary Dilatation Catheter	LPNRX25012
41	NC Tadpole™ Coronary Dilatation Catheter	LPNRX27012
42	NC Tadpole™ Coronary Dilatation Catheter	LPNRX30012
43	NC Tadpole™ Coronary Dilatation Catheter	LPNRX32012
44	NC Tadpole™ Coronary Dilatation Catheter	LPNRX35012
45	NC Tadpole™ Coronary Dilatation Catheter	LPNRX37012
46	NC Tadpole™ Coronary Dilatation Catheter	LPNRX40012
47	NC Tadpole™ Coronary Dilatation Catheter	LPNRX45012
48	NC Tadpole™ Coronary Dilatation Catheter	LPNRX50012
49	NC Tadpole™ Coronary Dilatation Catheter	LPNRX15015
50	NC Tadpole™ Coronary Dilatation Catheter	LPNRX20015
51	NC Tadpole™ Coronary Dilatation Catheter	LPNRX22015
52	NC Tadpole™ Coronary Dilatation Catheter	LPNRX25015
53	NC Tadpole™ Coronary Dilatation Catheter	LPNRX27015
54	NC Tadpole™ Coronary Dilatation Catheter	LPNRX30015
55	NC Tadpole™ Coronary Dilatation Catheter	LPNRX32015
56	NC Tadpole™ Coronary Dilatation Catheter	LPNRX35015
57	NC Tadpole™ Coronary Dilatation Catheter	LPNRX37015
58	NC Tadpole™ Coronary Dilatation Catheter	LPNRX40015
59	NC Tadpole™ Coronary Dilatation Catheter	LPNRX45015
60	NC Tadpole™ Coronary Dilatation Catheter	LPNRX50015
61	NC Tadpole™ Coronary Dilatation Catheter	LPNRX15020

NO	NAME OF DEVICE	IDENTIFIER
62	NC Tadpole™ Coronary Dilatation Catheter	LPNRX20020
63	NC Tadpole™ Coronary Dilatation Catheter	LPNRX22020
64	NC Tadpole™ Coronary Dilatation Catheter	LPNRX25020
65	NC Tadpole™ Coronary Dilatation Catheter	LPNRX27020
66	NC Tadpole™ Coronary Dilatation Catheter	LPNRX30020
67	NC Tadpole™ Coronary Dilatation Catheter	LPNRX32020
68	NC Tadpole™ Coronary Dilatation Catheter	LPNRX35020
69	NC Tadpole™ Coronary Dilatation Catheter	LPNRX37020
70	NC Tadpole™ Coronary Dilatation Catheter	LPNRX40020
71	NC Tadpole™ Coronary Dilatation Catheter	LPNRX45020
72	NC Tadpole™ Coronary Dilatation Catheter	LPNRX50020
73	NC Tadpole™ Coronary Dilatation Catheter	LPNRX15025
74	NC Tadpole™ Coronary Dilatation Catheter	LPNRX20025
75	NC Tadpole™ Coronary Dilatation Catheter	LPNRX22025
76	NC Tadpole™ Coronary Dilatation Catheter	LPNRX25025
77	NC Tadpole™ Coronary Dilatation Catheter	LPNRX27025
78	NC Tadpole™ Coronary Dilatation Catheter	LPNRX30025
79	NC Tadpole™ Coronary Dilatation Catheter	LPNRX32025
80	NC Tadpole™ Coronary Dilatation Catheter	LPNRX35025
81	NC Tadpole™ Coronary Dilatation Catheter	LPNRX37025
82	NC Tadpole™ Coronary Dilatation Catheter	LPNRX40025
83	NC Tadpole™ Coronary Dilatation Catheter	LPNRX45025
84	NC Tadpole™ Coronary Dilatation Catheter	LPNRX50025
85	NC Tadpole™ Coronary Dilatation Catheter	LPNRX15030
86	NC Tadpole™ Coronary Dilatation Catheter	LPNRX20030
87	NC Tadpole™ Coronary Dilatation Catheter	LPNRX22030

NO	NAME OF DEVICE	IDENTIFIER
88	NC Tadpole™ Coronary Dilatation Catheter	LPNRX25030
89	NC Tadpole™ Coronary Dilatation Catheter	LPNRX27030
90	NC Tadpole™ Coronary Dilatation Catheter	LPNRX30030
91	NC Tadpole™ Coronary Dilatation Catheter	LPNRX32030
92	NC Tadpole™ Coronary Dilatation Catheter	LPNRX35030
93	NC Tadpole™ Coronary Dilatation Catheter	LPNRX37030
94	NC Tadpole™ Coronary Dilatation Catheter	LPNRX40030
95	NC Tadpole™ Coronary Dilatation Catheter	LPNRX45030
96	NC Tadpole™ Coronary Dilatation Catheter	LPNRX50030



MEDICAL DEVICE AUTHORITY