



**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN**

Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950
Telepon : (021) 5201590 Pesawat 2029, 8011
Faksimile : (021) 52964838 Kotak Pos : 203



Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

ALAT KESEHATAN

KEMENKES RI AKL 30503220069

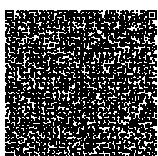
Nama Dagang / Merek : **HT Supreme™ Drug Coated Coronary Stent System**
Kelompok / Kelas Resiko : Non Elektromedik Steril / D
Kategori Produk : Peralatan Kardiologi
Sub Kategori : Peralatan Kardiologi Prostetik
Jenis Produk : Drug eluting stent
Tipe / Ukuran : Terlampir
Kemasan : Dus
Nama Produsen / Pabrikan : SINO MEDICAL SCIENCES TECHNOLOGY INC., China
Nama Pendaftar : PT. TARAFIS ANUGERAH MEDIKA, DKI Jakarta
Atas dasar lisensi dari : -

Ketentuan

1. Persetujuan izin edar berlaku sampai dengan 23 Juni 2027.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Izin edar ini merupakan persetujuan perubahan berupa penambahan tipe/ukuran produk dari Nomor Izin Edar Alat Kesehatan KEMENKES RI AKL 30503220069 tanggal 18 Juli 2022. Dengan demikian izin edar sebelumnya dinyatakan tidak berlaku.
4. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
5. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
6. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 22 November 2022

Ditandatangani Secara Elektronik Oleh :
Direktur Jenderal
Kefarmasian dan Alat Kesehatan
Dr. Dra. L. Rizka Andalucia, Apt., M.Pharm, MARS.
NIP. 19680226 199403 2 004



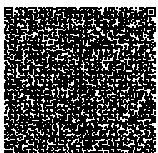


LAMPIRAN

NOMOR IZIN EDAR
ALAT KESEHATAN
KEMENKES RI AKL 30503220069

No.	Deskripsi	Tipe / Kode
1	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.50 mm & Length 10 mm)	BMA-2.5010
2	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.50 mm & Length 15 mm)	BMA-2.5015
3	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.50 mm & Length 20 mm)	BMA-2.5020
4	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.50 mm & Length 25 mm)	BMA-2.5025
5	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.50 mm & Length 30 mm)	BMA-2.5030
6	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.50 mm & Length 35 mm)	BMA-2.5035
7	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.75 mm & Length 10 mm)	BMA-2.7510
8	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.75 mm & Length 15 mm)	BMA-2.7515
9	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.75 mm & Length 20 mm)	BMA-2.7520
10	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.75 mm & Length 25 mm)	BMA-2.7525
11	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.75 mm & Length 30 mm)	BMA-2.7530
12	HT Supreme™ Drug Coated Coronary Stent System (Diameter 2.75 mm & Length 35 mm)	BMA-2.7535
13	HT Supreme™ Drug Coated Coronary Stent System (Diameter 3.00 mm & Length 10 mm)	BMA-3.0010
14	HT Supreme™ Drug Coated Coronary Stent System (Diameter 3.00 mm & Length 15 mm)	BMA-3.0015
15	HT Supreme™ Drug Coated Coronary Stent System (Diameter 3.00 mm & Length 20 mm)	BMA-3.0020
16	HT Supreme™ Drug Coated Coronary Stent System (Diameter 3.00 mm & Length 25 mm)	BMA-3.0025
17	HT Supreme™ Drug Coated Coronary Stent System (Diameter 3.00 mm & Length 30 mm)	BMA-3.0030
18	HT Supreme™ Drug Coated Coronary Stent System (Diameter 3.00 mm & Length 35 mm)	BMA-3.0035
19	HT Supreme™ Drug Coated Coronary Stent System (Diameter 3.25 mm & Length 10 mm)	BMA-3.2510
20	HT Supreme™ Drug Coated Coronary Stent System (Diameter 3.25 mm & Length 15 mm)	BMA-3.2515
21	HT Supreme™ Drug Coated Coronary Stent System (Diameter 3.25 mm & Length 20 mm)	BMA-3.2520

Lampiran 1 dari 3 Halaman





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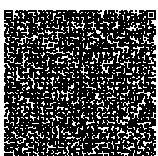
Telepon : (021) 5201590 Pesawat 2029, 8011

Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
22	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.25 mm & Length 25 mm)	BMA-3.2525
23	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.25 mm & Length 30 mm)	BMA-3.2530
24	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.25 mm & Length 35 mm)	BMA-3.2535
25	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.50 mm & Length 10 mm)	BMA-3.5010
26	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.50 mm & Length 15 mm)	BMA-3.5015
27	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.50 mm & Length 20 mm)	BMA-3.5020
28	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.50 mm & Length 25 mm)	BMA-3.5025
29	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.50 mm & Length 30 mm)	BMA-3.5030
30	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.50 mm & Length 35 mm)	BMA-3.5035
31	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.00 mm & Length 10 mm)	BMA-4.0010
32	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.00 mm & Length 15 mm)	BMA-4.0015
33	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.00 mm & Length 20 mm)	BMA-4.0020
34	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.00 mm & Length 25 mm)	BMA-4.0025
35	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.00 mm & Length 30 mm)	BMA-4.0030
36	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.00 mm & Length 35 mm)	BMA-4.0035
37	HT Supreme TM Drug Coated Coronary Stent System (Diameter 2.25 mm & Length 10 mm)	BMA-2.2510
38	HT Supreme TM Drug Coated Coronary Stent System (Diameter 2.25 mm & Length 15 mm)	BMA-2.2515
39	HT Supreme TM Drug Coated Coronary Stent System (Diameter 2.25 mm & Length 20 mm)	BMA-2.2520
40	HT Supreme TM Drug Coated Coronary Stent System (Diameter 2.25 mm & Length 25 mm)	BMA-2.2525
41	HT Supreme TM Drug Coated Coronary Stent System (Diameter 2.25 mm & Length 30 mm)	BMA-2.2530
42	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.50 mm & Length 10 mm)	BMA-4.5010
43	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.50 mm & Length 15 mm)	BMA-4.5015
44	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.50 mm & Length 20 mm)	BMA-4.5020
45	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.50 mm & Length 25 mm)	BMA-4.5025

Lampiran 2 dari 3 Halaman





**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
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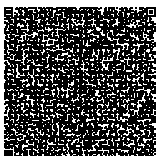
Faksimile : (021) 52964838 Kotak Pos : 203



No.	Deskripsi	Tipe / Kode
46	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.50 mm & Length 30 mm)	BMA-4.5030
47	HT Supreme TM Drug Coated Coronary Stent System (Diameter 5.00 mm & Length 10 mm)	BMA-5.0010
48	HT Supreme TM Drug Coated Coronary Stent System (Diameter 5.00 mm & Length 15 mm)	BMA-5.0015
49	HT Supreme TM Drug Coated Coronary Stent System (Diameter 5.00 mm & Length 20 mm)	BMA-5.0020
50	HT Supreme TM Drug Coated Coronary Stent System (Diameter 5.00 mm & Length 25 mm)	BMA-5.0025
51	HT Supreme TM Drug Coated Coronary Stent System (Diameter 5.00 mm & Length 30 mm)	BMA-5.0030
52	HT Supreme TM Drug Coated Coronary Stent System (Diameter 2.50 mm & Length 40 mm)	BMA-2.5040
53	HT Supreme TM Drug Coated Coronary Stent System (Diameter 2.75 mm & Length 40 mm)	BMA-2.7540
54	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.00 mm & Length 40 mm)	BMA-3.0040
55	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.25 mm & Length 40 mm)	BMA-3.2540
56	HT Supreme TM Drug Coated Coronary Stent System (Diameter 3.50 mm & Length 40 mm)	BMA-3.5040
57	HT Supreme TM Drug Coated Coronary Stent System (Diameter 4.00 mm & Length 40 mm)	BMA-4.0040

Dengan ketentuan bahwa izin edar tersebut hanya berlaku untuk deskripsi dan tipe / kode produk yang tercantum dalam lampiran ini

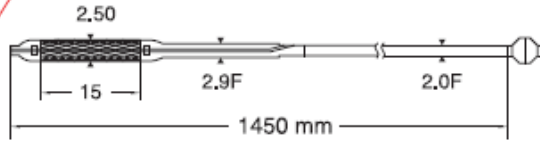
Jakarta, 22 November 2022



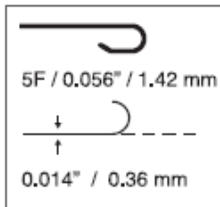
Hy SUPREME™

Drug Coated Coronary Stent System / Medikamentenbeschichtetes Koronarstentssystem / Sistema de stent coronario recubierto de fármaco / Système d'endoprothèse coronaire à revêtement médicamenteux / Sistem Stent Koronar Berbasis Obat / Sistema stent coronario revestido el fármaco / Coronair stentstelsysteem met geneesmiddelencoating / Sistema de Stent Coronário Revestido por Fármaco / 藥物塗層冠狀動脈支架系統

2.50 15



Pressure (atm)	Pressure (kPa)	Diameter (mm)
8	811	2.38
9	912	2.45
10	1013	NP 2.50
11	1115	2.57
12	1216	2.62
13	1317	2.66
14	1419	2.70
15	1520	2.73
16	1621	2.77
17	1723	2.81
18	1824	RBP 2.85



Hy SUPREME™ [RX] 2,50 mm x 15 mm

(01) 0 6948546 20514 1

(17)14 1119 (21) 305023101

[SN] 305023101 [Exp] 2014 - 11 - 19
[REF] BMA-2,5015

SINO MED

Hy SUPREME™ [RX] 2,50 mm x 15 mm

(01) 0 6948546 20514 1

(17)14 1119 (21) 305023101

[SN] 305023101 [Exp] 2014 - 11 - 19
[REF] BMA-2,5015

SINO MED

Hy SUPREME™ [RX] 2,50 mm x 15 mm [SN] 305023101 [REF] BMA-2,5015 SINO MED	Hy SUPREME™ [RX] 2,50 mm x 15 mm [SN] 305023101 [REF] BMA-2,5015 SINO MED
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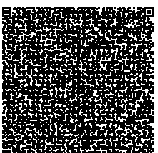
Hy SUPREME™ [RX]
2,50 mm x 15 mm
[SN] 305023101
[REF] BMA-2,5015
SINO MED



0.007.0185

SINO MED

Figure 4 Inner Package Label



RX

SUPREME™ Drug Coated
Coronary Stent System

2.50

15

RX

SUPREME™ 2.50 **15**

REF BMA-2.5015

0514 141119305023101

RX

SUPREME™ 2.50 **15**

SN 305023101

REF BMA-2.5015

Use By 2014-11-19 (YYYY-MM-DD)

Date of manufacture 2013-05-20

Drug Coated Coronary Stent System / Medikamentenbeschichtetes Koronarstentsystem / Sistema de stent coronario recubierto de fármaco / Système d'endoprothèse coronaire à revêtement médicamenteux / Sistem Stent Koronar Berbasis Obat / Sistema stent coronario rivestito di farmaco / Coronair stentsysteem met geneesmiddelcoating / Sistema de Stent Coronario Revestido por Fármaco / 藥物塗層冠狀動脈支架系統

2.50

15

2.9F

2.0F

1450 mm

5F / 0.056" / 1.42 mm

0.014" / 0.36 mm

Pressure		Diameter
(atm)	(kPa)	(mm)
8	811	2.38
9	912	2.45
10	1013	NP 2.50
11	1115	2.57
12	1216	2.62
13	1317	2.66
14	1419	2.70
15	1520	2.73
16	1621	2.77
17	1723	2.81
18	1824	RBP 2.85

Hy SUPREME™ [RX] 2.50 mm x 15 mm

(01) 0 6948546 20514 1

(17)14 1119 (21) 305023101

SN 305023101 Use By 2014-11-19 (YYYY-MM-DD)

REF BMA-2.5015

sinomed

Hy SUPREME™ [RX] 2.50 mm x 15 mm

(01) 0 6948546 20514 1

(17)14 1119 (21) 305023101

SN 305023101 Use By 2014-11-19 (YYYY-MM-DD)

REF BMA-2.5015

sinomed

Hy SUPREME™ [RX] 2.50 mm x 15 mm

(01) 0 6948546 20514 1

(17)14 1119 (21) 305023101

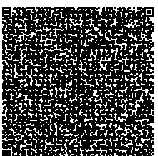
SN 305023101 Use By 2014-11-19 (YYYY-MM-DD)

REF BMA-2.5015

sinomed

0.007.0186

Figure 3 Outer Package Label



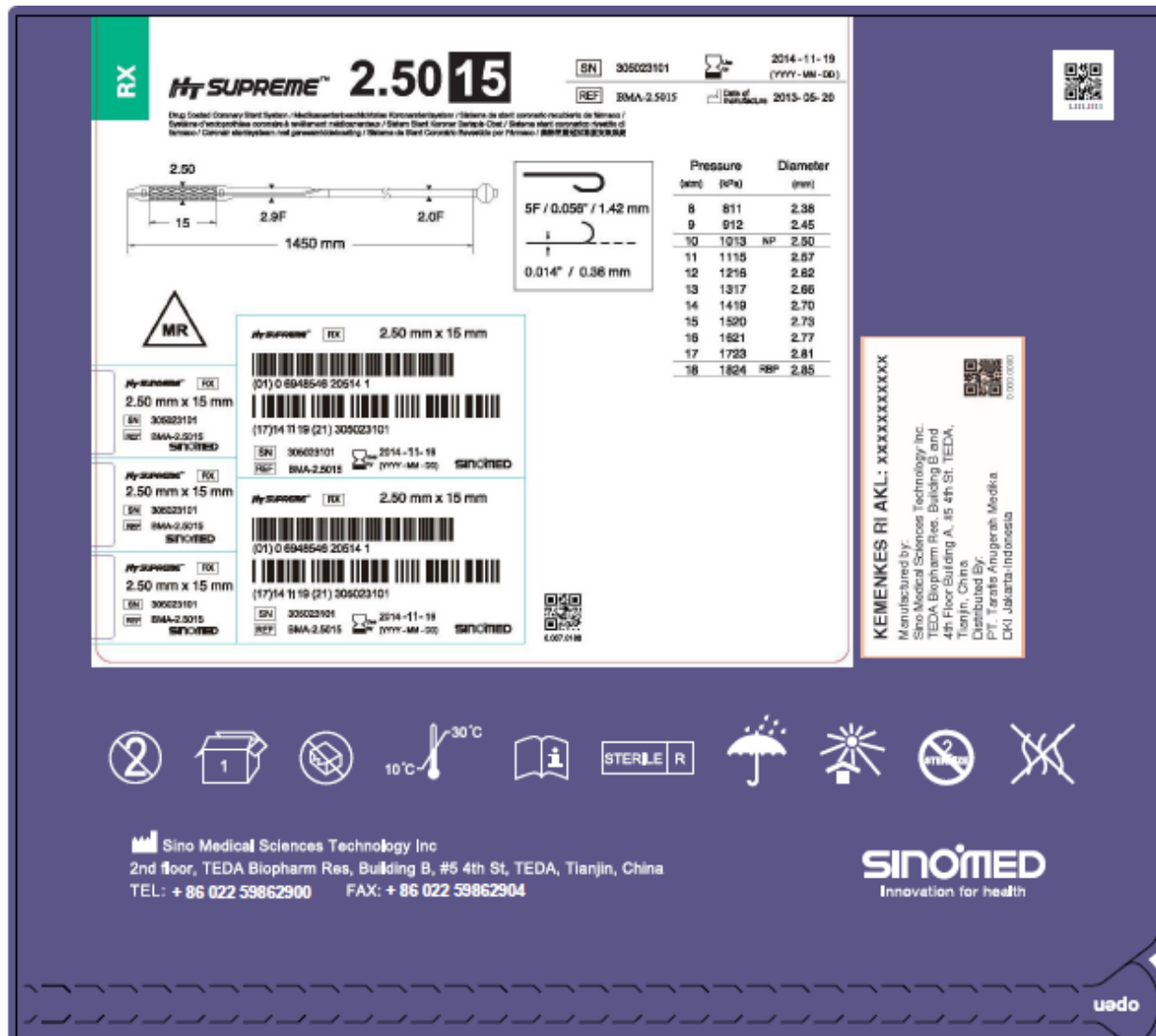


Figure 6 Photo of the Outer Package Label – Back

