



**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 20101123760

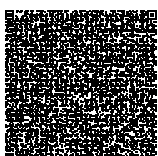
Nama Dagang / Merek : **SINOCARE Portable Automatic Multi-Function Analyzer iCARE-2100**
Kelompok / Kelas Resiko : Diagnostik *In Vitro* / C
Kategori Produk : Peralatan Kimia Klinik dan Toksikologi Klinik
Sub Kategori : Sistem Tes Kimia Klinik
Jenis Produk : Multi parameter clinical chemistry test system
Tipe / Ukuran : iCARE-2100
Kemasan : Box, unit
Nama Produsen / Pabrikan : CHANGSHA SINOCARE INC., China
Nama Pendaftar : PT. SINOCARE HEALTHCARE INDONESIA, DKI Jakarta
Atas dasar lisensi dari : -

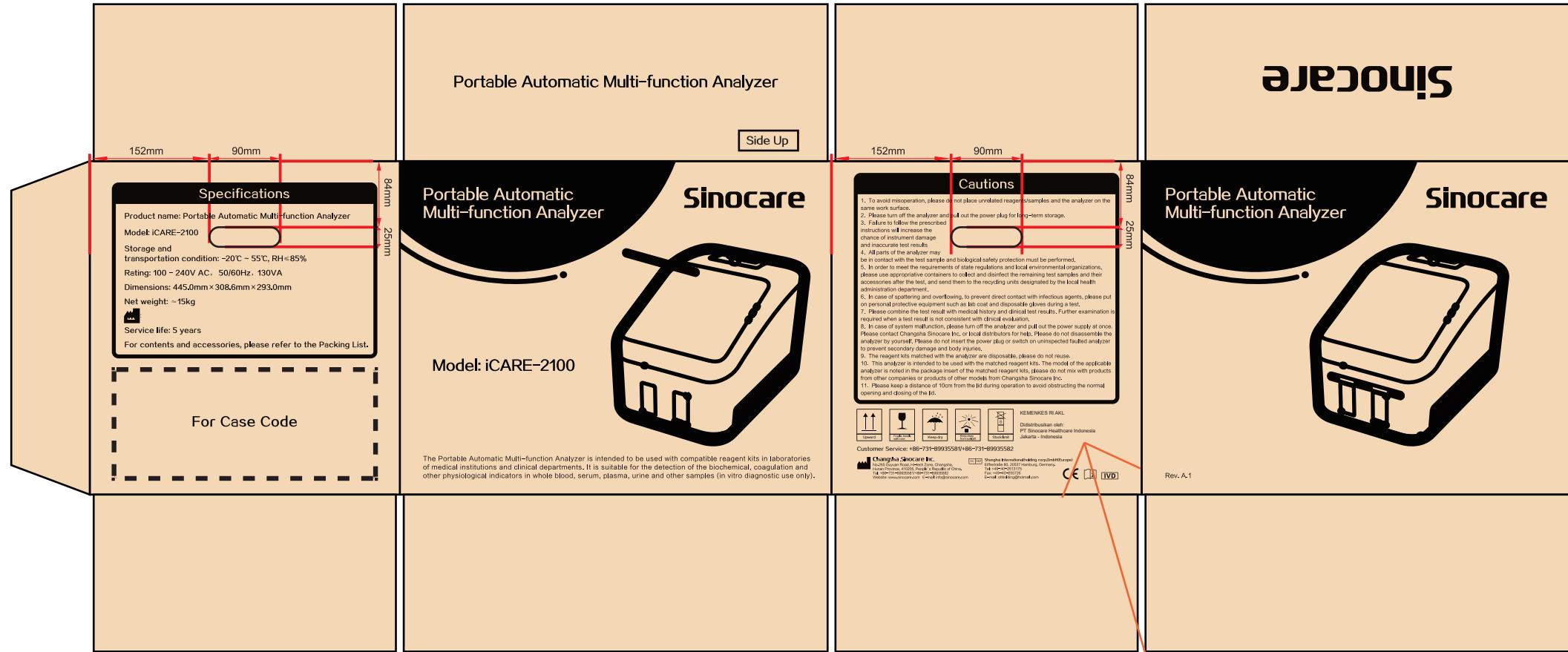
Ketentuan

1. Persetujuan izin edar berlaku .
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 perpanjangan dari Nomor Izin Edar Alat Kesehatan KEMENKES RI AKL 20101123760 tanggal 27 Juni 2021. 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.

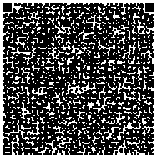
Jakarta, 29 November 2023

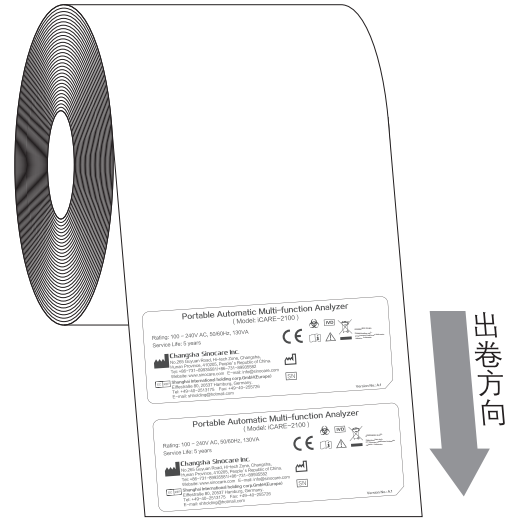
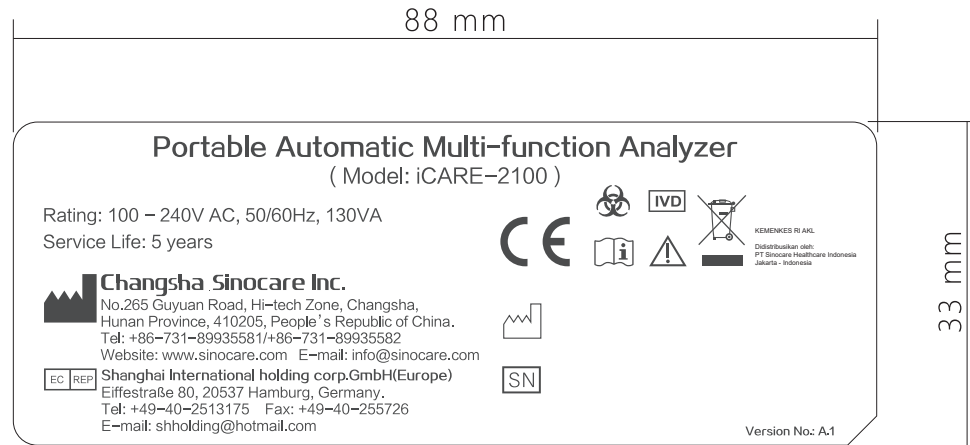
Ditandatangani Secara Elektronik Oleh :
Direktur Jenderal
Kefarmasian dan Alat Kesehatan
Dr. Dra. L. Rizka Andalucia, Apt., M.Pharm, MARS.
NIP. 19680226 199403 2 004





图文尺寸 内空: 550(L)*395(W)*425(H)
(请优先保证内空尺寸)



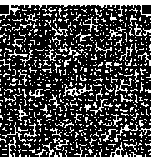
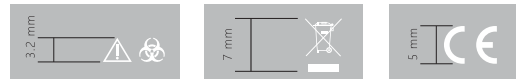


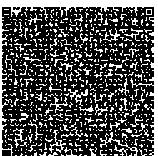
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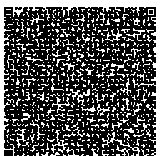
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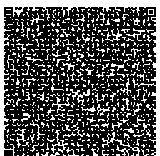
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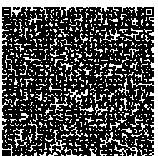
• 最小尺寸：最小不低于如下尺寸





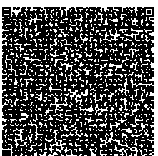








Model: CA9E-2150
Portable Automatic Multi-function Analyzer
(Model: CA9E-2150)
Rating: 100-240V AC, 50/60Hz, 160W
Service Life: 5 years
Warranty: 3 years
Changsha Sincere Inc.
No. 10, Changsha Avenue, Changsha, Hunan, China
Tel: 86-731-88822111 / 88822112
Website: www.sincere.com.cn
E-mail: info@sincere.com.cn





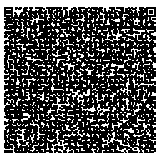
WP-PE-VPO

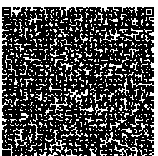
Portable Automatic Multi-function Analyzer
(Model: ICARE-2100)

Rating: 100 ~ 240V AC, 50/60Hz, 160W
Service Life: 5 years
(Functional Earth)

Changsha Sinocare Inc.
NO.285, Guyuan Road, Hi-tech Zone, Changsha,
Hunan Province 410205, People's Republic of China.
Tel: +86-731-89935581/86-731-89935582
Website: www.sinocare.com
E-mail: info@sinocare.com

Icons: CE, RoHS, WEEE, IEC60950, IVD, SN





iCARE-2100

**Portable
Analyzer**

Automatic

Multi-function

Specification

CE



Item	Specification
Language	English/Simplified Chinese
Display	9.7-inch touch screen, 1024*768 pixels
Communication interface	USB (x2), LAN (x1), RS232 (x1)
WIFI	Implement IEEE 802.11b/g/n standard
Rating	100 - 240V AC, 50/60 Hz, 130 VA
Size	445.0mm×293.0mm×308.6mm
Net weight	< 15kg;
Printer	Built-in thermal printer
Measuring system	Light transmission system, fluorescence system, light reflection system
Wavelength of light sources	340nm,405nm,455nm,505nm,546nm,578nm,630nm,635nm,660nm,700nm, etc.
Internal working temperature	37°C ±0.5°C
Data storage	80000 sample test results, 10000 QC test results
Noise	≤65 dBA
Operating altitude	Max. 2000m
Overvoltage category	Category II
Pollution degree of the intended environment	Pollution degree 2
Service life	5 years The service life of the analyzer is determined by the service life of the main components. During the period of use, the user should maintain the analyzer complying with the requirements of this user manual. After maintenance, normal operation can be performed when its safety and effectiveness are verified.
Fuse-link (mains)	T2AL250VAC, 5x20mm
Date of manufacture	See label for date of manufacture
Software release version	V01

