



**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 20205020724

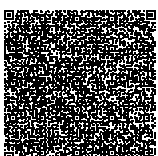
Nama Dagang / Merek : **SINOCARE PCH-100 HbA1c Analyzer**
Kelompok / Kelas Resiko : Diagnostik *In Vitro* / B
Kategori Produk : Peralatan Hematologi dan Patologi
Sub Kategori : Paket dan Kit Hematologi
Jenis Produk : Glycosylated hemoglobin assay.
Tipe / Ukuran : PCH-100
Kemasan : Dus, unit
Nama Produsen / Pabrikasi : CHANGSHA SINOCARE INC., China
Nama Pendaftar : PT. ISOTEKINDO INTERTAMA, DKI Jakarta
Atas dasar lisensi dari : -

Ketentuan

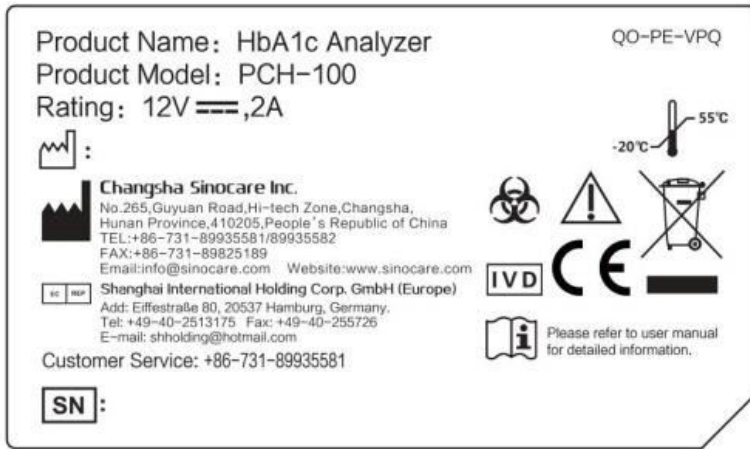
1. Persetujuan izin edar berlaku
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Izin edar ini merupakan persetujuan perpanjangan dari Nomor Izin Edar Alat Kesehatan KEMENKES RI AKL 20205020724 tanggal 6 Maret 2020. 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, 26 September 2022

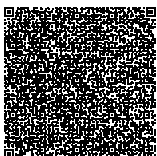
Ditandatangani Secara Elektronik Oleh :
a.n Direktur Jenderal
Direktur Produksi dan Distribusi Alat Kesehatan
Ir. Sodikin Sadek, M.Kes
NIP. 19621203 198603 1 004



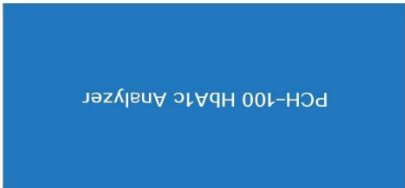
GAMBAR KEMASAN PRIMER



Marking Plate terletak di bawah Alat



GAMBAR KEMASAN SEKUNDER



Technical Specifications

Product Name: HbA1c Analyzer
 Product Model: PCH-100
 Rating: 12V 2A
 Size: 250mm x 235mm x 126mm
 Net Weight: ≤1.3kg
 Transportation and Storage conditions: -20°C-55°C

LOT: 2TJMN

Changsha Sinocare Inc.
 No. 295, Gouyuan Road, Hi-Tech Zone, Changsha, Hunan Province, 410205, People's Republic of China
 TEL: +86-731-88935581/88935582
 FAX: +86-731-88925189
 Email: info@sinocare.com Website: www.sinocare.com

Shanghai International Holding Corp. GmbH (Europe)
 Eilfeinstrasse 80, 20037 Hamburg, Germany
 Tel: +49-40-2513175 Fax: +49-40-256726
 E-mail: shholding@vivaldi.com

QO-PE-VPQ

Sinocare PCH-100 HbA1c Analyzer

- Easy Operation
- Compact & Portable
- High-speed

IVD The HbA1c Analyzer PCH-100 is intended to be used with HbA1c Reagent Kit manufactured by Changsha Sinocare Inc. to quantitatively determine hemoglobin A1c (HbA1c) in capillary (fingerprick) or venous whole blood. It is for in vitro diagnostic use only. Clinically, it is mainly used for auxiliary diagnosis of diabetes and monitoring of average blood glucose level.

Cautions

- Please read the User Manual carefully before test.
- For in vitro diagnostic use only.
- Applicable for HbA1c Reagent Kit manufactured by Changsha Sinocare Inc.
- Please turn off the analyzer and pull out the power plug for long-term storage.
- Follow the local biohazard control standard when disposing samples and their appendant.
- In case of spattering and overflowing, to make preparation against direct contact with infectious agents, please put on personal protective equipment such as lab coat and disposable gloves during a test.
- In case of system malfunction, please turn off the analyzer and pull out the power supply at once. Please contact Changsha Sinocare Inc. or local distributors for help. Please do not disassemble the analyzer by yourself. Please do not insert the power plug or switch on uninspected faulted analyzer to prevent secondary damage and body injuries.

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CE Please refer to user manual for detailed information.

红色版不印刷

Sinocare三谱		符合HSE标准	
公司名称	三谱生物科技股份有限公司	物料编码	36200391
文件名称	PO-PE-VPQ 英文说明书及中文说明书	物料名称	物料名称
版本编号	QO-PE-VPQ	公差	按图物控标准
图文尺寸	单位: 毫米 (mm)	设计日期	2019年03月
制作材料	彩色与黑色印刷, 无底纹, 避免加底纹, 避免出血	修改次序	第 1 次设计
设计人	曹程健	2019年03月28日	
审核人			

Letak No AKL, Nama Distributor

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QO-PE-VPQ

Sinocare PCH-100 HbA1c Analyzer

HbA1c Analyzer PCH-100
 No. Reg. Alat Kesehatan KEMENKES RI AKL 0000000000
 PT Istokindo Intertama
 Jakarta - Indonesia

- Easy Operation
- Compact & Portable
- High-speed

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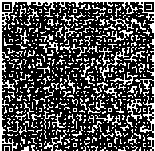
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GAMBAR PRODUK



SPESIFIKASI PRODUK

Item	Spesifikasi
Jenis sampel	Darah kapiler (segar), darah vena <i>whole blood</i>
Ukuran Sampel	5 uL
Reagen Pendukung	Reagen HbA1c Kit , yang diproduksi oleh Changsha Sinocare Inc.
Bahasa	Bahasa Inggris / Mandarin (China)
Layar	Layar sentuh LCD 4,3 inci , 480 x 272 piksel
Konektor	RS232 (x1), USB (x1)
WIFI	Standard IEEE 802.11/b/g/n
Bluetooth	4.0
Arus Listrik	12V, 2A
Kategori Tegangan	Kategori II (untuk adaptor AC /DC)
Layar	Layar sentuh LCD 4,3 inci , 480 x 272 piksel
Ukuran /Dimensi	250 mm x 235 mm x 126 mm
Berat	<3,5 Kg
Printer	Printer termal , terintegrasi
Sistem Pengukuran	Sistem kolorimetri
Waktu Pengukuran	≤ 3,5 menit
Simpanan Data	1000 hasil tes, 200 hasil tes QC
Kondisi Operasional	15 °C ~ 35 °C, 15% ~ 90% RH, hanya digunakan di dalam ruangan
Altitude Operasional	Maks. 2000 m
Kondisi Transportasi dan Penyimpanan	-20 °C - 55 °C
Versi perangkat lunak	V1

