



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

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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 21403122750

Nama Dagang / Merek : **H/P/COSMOS Treadmill Ergometer**
Kelompok / Kelas Resiko : Elektromedik Non Radiasi / B
Kategori Produk : Peralatan Kesehatan Fisik
Sub Kategori : Peralatan Kesehatan Fisik Terapetik
Jenis Produk : Powered exercise equipment.
Tipe / Ukuran : Mercury® med
Kemasan : Unit
Nama Produsen / Pabrikan : H/P/COSMOS SPORTS & MEDICAL GMBH, Germany
Nama Pendaftar : PT. MURTI INDAH SENTOSA, DKI Jakarta
Atas dasar lisensi dari : -

Ketentuan

1. Persetujuan izin edar berlaku sampai dengan 30 November 2023.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
4. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
5. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 09 Mei 2021

	<p>Ditandatangani Secara Elektronik Oleh :</p> <p>a.n Direktur Jenderal Direktur Penilaian Alat Kesehatan dan PKRT</p> <p>Dr. IGM. Wirabratna, Apt NIP. 19751206 200312 1 001</p>
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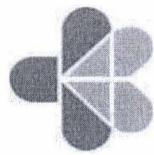


Catatan:

- UU ITE No 11 Tahun 2008 Pasal 5 ayat 1

Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.

- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSfE.



MINISTRY OF HEALTH OF THE REPUBLIC OF INDONESIA
DIRECTORATE GENERAL OF PHARMACEUTICALS AND
HEALTH DEVICES



Jalan H.R. Rasuna Said Blok X-5 Kaveling 4 - 9 Jakarta 12950

Phone: (021) 5201590 Ext. 2029, 8011

Facsimile: (021) 52964838 Zip Code: 203

Based on Regulation of the Minister of Health of the Republic of Indonesia Number 62 of 2017 regarding Circulation Permit of Health Devices and Medical devices, it is hereby issued approval for circulation with:

CIRCULATION PERMIT NUMBER

MEDICAL DEVICES

KEMENKES RI AKL 21403122750

Trade Name/Mark : H/P/COSMOS Treadmill Ergometer
Risk Group/Class : Non Radiation Electro-medical/B
Product Category : Physical Health Equipment
Sub Category : Therapeutic Physical Health Equipment
Product Type : Powered exercise equipment.
Type/Size : Mercury® med
Package : Unit

Producer/Factory Name: H/P/COSMOS SPORTS & MEDICAL GMBH, Germany

Registrant : PT. MURTI INDA0 SENTOSA, DKI Jakarta

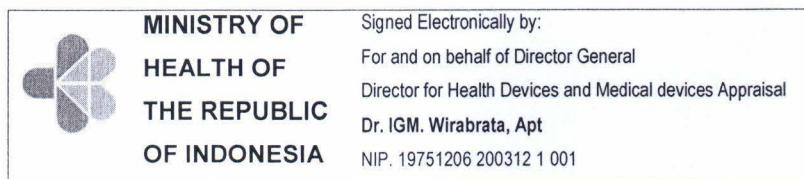
Based on license from: -

Provisions



1. Approval of circulation permit shall be valid until November 30, 2023.
2. Shall submit the periodical report and the report in case of undesired event as the consequence of use of PKRT above in accordance with the prevailing provisions.
3. If in the future there is the other party more entitled to brand and/or agency of product above, the applicant shall be prepared to return the circulation permit.
4. The marking and information on product enclosed shall form integral part of this approval of circulation permit.
5. If in the future there is mistake, then this approval of circulation permit will be subjected to review.

Jakarta, May 09, 2021



Notes:

- Law on No 11 of 2007 Article 5(1)
Electronic Information and/or Electronic Document and/or their printouts are valid legal evidence.
- This document has been signed electronically by using electronic certificate issued by BSrE.

I, Eko Tjahyadi, Sworn & Certified Translator and team, hereby declare that this document is an English translation of a document prepared in Indonesian language. In translating this document an attempt has been made to translate as literally as possible without jeopardizing the overall continuity of the text. However differences may occur in translation and if they do the original text has precedence in law.

Jakarta, May 19, 2021

