

INMOVILIZADOR DE CABEZA



Características:

- Inmovilizador de cabeza lateral fabricado en espuma de alta densidad recubierta por engomado hidrófuga.
- Desmontable ajustable con velcro de alta duración.
- Fácil lavado.
- Material Hipo Alergénico.
- La unidad viene completa con Base, dos almohadillas de apoyo (laterales) y correas para el mentón y cabeza.
- Translúcido: No interfiere con rayos X, resonancia magnética o procedimientos CT
- No absorbe sangre ni fluidos corporales.
- Orificio a la altura de los oídos, lo que permite un fácil monitoreo.

Certificaciones:

- EN ISO 1941:2012 - EN 1041:2008
- EN ISO 10993-1:2009
- EN ISO 10993-5:2009
- EN ISO 10993-10 EN 980:2008

Descripción:

Inmovilizador lateral de cabeza es perfecto para ser utilizado en tablas espinales, fabricado en espuma de alta densidad con determinación engomada permite permeabilidad completa del equipo.

Su parte posterior con refuerzo acolchado permite suavizar la prolongada permanencia de cabeza del paciente.

PRODUCTO IMPORTADO

Usos:

- Rescate.
- Cruz roja.
- Industria.
- Bomberos.
- Agroquímicos.
- Construcción.
- Minería.
- Hospitalaria.
- Canteras.
- Automotriz.
- Obra civil.

Ni el vendedor ni el fabricante serán responsables de cualquier lesión personal, pérdida o daños ya sean directos o consecuentes del mal uso de este producto. Antes de ser usado, se debe determinar si el producto es apropiado para el uso pretendido.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Certificate No. 21545-3-2024

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

CERTIFICATE TO FOREIGN GOVERNMENT
In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

Head Immobilizer _ KARLYS

Name of Manufacturer/Distributor, Address

Manufacturer/Distributor:

Wuxi Medcare Technology CO., LTD.

Main Site: Wuzhou Industrial City C, Youyi Road,
Xishan Economic Development Zone, Wuxi, China

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Ann M. Ferriter
Director
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

Subscribed and sworn to before me this 9 day of April month 2024 year.



Certificate of Registration

Intertek

This is to certify that the quality management system of

Wuxi Medcare Technology CO., LTD.

Main Site: Wuzhou Industrial City C, Youyi Road,
Xichan Economic Development Zone, Wuxi, China

has been assessed and registered by Intertek, a Head in immobiliser Zarja, as conforming to the requirements of

ISO 13485:2003

The quality management system is applicable to

Design, manufacture, distributor of patient transport equipment, fire and emergency rescue and response equipment, head and cervical immobilization
and splinting devices, distribution of emergency respiratory care products

Certificate Number: 22045-0004


Christopher Mun, President

Wuxi Medcare Technology CO., LTD - Liushan QC, China



In the course of this certificate, Intertek's agents are liable to inspect the place of Client, and then only in accordance with its own Certification Agreement. This certificate is not transferable. It is the responsibility of the Client to inform Intertek of any change in accordance with the terms and conditions for further certification. Valid until the date mentioned.

The certificate remains the property of Intertek, to whom it must be returned upon request.

Intertek Intertek Intertek Intertek Intertek



Siguenos:



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RAZON SOCIAL:
V&M SAFETY PERU S. A. C.
R.U.C.: 20612313441