



Ficha Técnica

Bolsa de Bicarbonato en Polvo 650g - 900g



NATURALEZA Y CONTENIDO DEL ENVASE

Nombre del Producto: Bolsa hermética 650 y 900 g

Embalaje y Unidad de Empaque: 20 unidades (bolsa) por caja.

Fabricante: Tiajin Taishikang Pharmaceutical Technology Co.,Ltd.

Distribuido por: Inversiones Masai Mara SpA (Medical Supply).

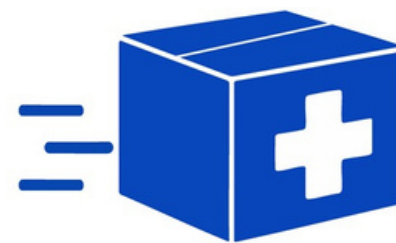
Procedencia: China.



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www.medicalsupply.cl



BICARBONATO EN POLVO

El producto es una materia prima dedicada a la preparación de hemodiálisis, utilizada para limpiar los desechos metabólicos en el cuerpo y mantener el equilibrio ácido base. El producto corresponde a concentrado bicarbonato seco de 650 y 900 gramos, contenido en una bolsa hermética compatible con monitores Fresenius 4008S y 5008 de fácil manipulación, con cierre hermético que disminuye el riesgo de contaminación y crecimiento bacteriano.

CARACTERÍSTICAS DEL PRODUCTO

100% Bicarbonato de Sodio.

Na+: 35 mmol/L.

HCO₃⁻: 35 mmol/L.

ADMINISTRACIÓN Y CONTRAINDICACIONES

Polvo liofilizado y estabilizado para dilución en línea compatible con equipos de hemodiálisis marca Fresenius 4008S y 5008. Compatible con dilución 1:34 (35X) y 1:44 (45X).

TRAZABILIDAD/CERTIFICADOS/REGISTROS

Lote de fabricación en etiqueta : Sí.

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Sello de Inviolabilidad : Sí.

Rótulo de Esterilización : No.

Método de Esterilización : No aplica.

Periodo de Vigencia : 3 años a partir de la fecha de fabricación.

Condiciones de almacenamiento : Lugar seco, libre de humedad y sin agua.

Condiciones de temperatura : Almacenaje +5°C a +30°C.

GARANTÍAS Y POLÍTICAS DE CANJE

Los productos con defectos de fabricación serán repuestos si se reporta el defecto junto con su número de lote. El fabricante no se responsabiliza en caso de mal uso, manejo inadecuado, no cumplimiento de las instrucciones de uso y seguridad, ni de ningún daño provocado posteriormente a la entrega del producto.



Certificate

No. Q5 086784 0004 Rev. 01

Holder of Certificate: **Tianjin Taishikang Pharmaceutical Technology Co., Ltd.**
No.10 Gangxin Road, Shuanggang Town, Jinnan District
300350 Tianjin
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): **Tianjin Taishikang Pharmaceutical Technology Co., Ltd.**
No.10 Gangxin Road, Shuanggang Town, Jinnan District,
300350 Tianjin, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of Concentrates for Haemodialysis (Dialysis Fluid and Dialysis Powder), Disinfectants for Haemodialysis Equipment (Citric Acid Disinfectant, Peracetic Acid Disinfectant, Sodium Hypochlorite Disinfectant, Citric Acid DisinfecCart and Sodium Carbonate CleanCart).**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 086784 0004 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_086784_0004_Rev_01)

Report No.: BJ24083401
Valid from: 2024-11-23
Valid until: 2027-11-22

Date, 2024-10-08



Christoph Dicks
Head of Certification/Notified Body



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 086784 0005 Rev. 00

Manufacturer: **Tianjin Taishikang Pharmaceutical
Technology Co., Ltd.**
No.10 Gangxin Road, Shuanggang Town, Jinnan District
300350 Tianjin
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000016030

**Authorized
Representative:** Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 086784 0005 Rev. 00

Report No.: BJ21083403

Valid from: 2022-06-15

Valid until: 2027-06-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-06-15



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
 (Class IIa and Class IIb Devices)

No. G10 086784 0005 Rev. 00

Classification: IIb
Device Group: F040101 - DIALYSIS CONCENTRATES, ACID SOLUTIONS, NON-STERILE
Intended Purpose: Concentrates for haemodialysis are dedicated products for preparation haemodialysis dialysate.

Classification: IIb
Device Group: F040201 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, POWDER
Intended Purpose: Concentrates for haemodialysis are dedicated products for preparation haemodialysis dialysate.

The validity of this certificate depends on conditions and/or is limited to the following: -none-