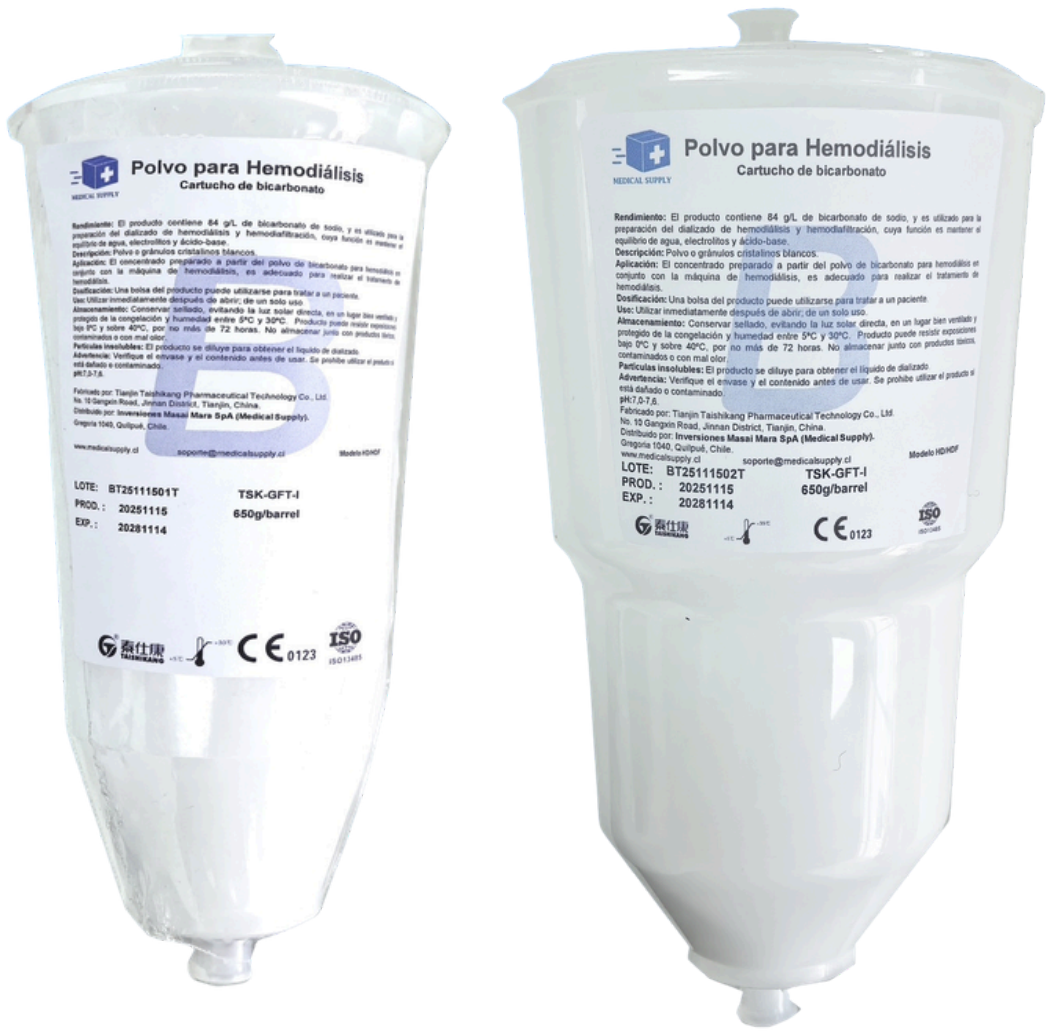
Medical Supply

Ficha Técnica

Cartucho de Bicarbonato en Polvo
650g - 900g



NATURALEZA Y CONTENIDO DEL ENVASE

Nombre del Producto: Cartucho (cartridge) 650 y 900g.

Empaque: 10 unidades por caja, Medida (38,8X25X21), Peso 7,9 Kg.

Fabricante: Tiajin Taishikang Pharmaceutical Technology Co., Ltd.

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

Certificación: ISO 13485:2016.

Procedencia: China.

soporte@medicalsupply.cl

www.medicalsupply.cl

泰仕康 TAISHIKANG

Medical Supply

BICARBONATO EN POLVO

El producto es una materia prima empleada en la preparación del tratamiento de hemodiálisis, destinada a eliminar los desechos metabólicos del organismo y mantener el equilibrio ácido-base. Se presenta como un concentrado de bicarbonato seco en presentación de 650 y 900 gramos, envasado en un cartucho hermético compatible con monitores que cuentan con soporte para cartucho de bicarbonato. Su diseño ergonómico facilita la manipulación, mientras que el cierre hermético minimiza el riesgo de contaminación y proliferación bacteriana.

CARACTERÍSTICAS DEL PRODUCTO

100% Bicarbonato de Sodio.	Na+: 35 mmol/L.	HCO3-: 35 mmol/L.

ADMINISTRACIÓN Y CONTRAINDICACIONES

Para ser utilizado en tratamientos de hemodiálisis o hemodiafiltración con bicarbonato en pacientes que requieran TRR. Compatible con máquinas B.Braun, Gambro, Nipro, SWS o cualquier monitor con módulo compatible.
Permite la dosificación exacta de bicarbonato a administrar.
Compatible con dilución 1:34 (35X) y 1:44 (45X)

TRAZABILIDAD/CERTIFICADOS/REGISTROS

Lote de fabricación en etiqueta	**:** Sí.
Fecha de Vencimiento en etiqueta	**:** Sí.
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.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

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

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

Date, 2024-10-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

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-

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