



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

DECLARACIÓN DE CONFORMIDAD

En nombre y representación de la firma ALCAT S.A., declaramos bajo juramento, en los términos previstos por la Disposición ANMAT N° 2198/22, que los Productos Médicos para Diagnóstico de Uso In-Vitro cuyos datos identificatorios y demás características se detallan a continuación, CUMPLEN los requisitos técnicos previstos en el Anexo I de la Disposición ANMAT N° 2674/99, conservándose la documentación respaldatoria a disposición de las autoridades en el domicilio de la empresa.

Número de PM:

1680-46

Nombre técnico del producto:

14-183 Tubos, para Recolección de Sangre

Nombre comercial:

SOL - M - Tubo de recolección de sangre

Modelos:

BCTPL001 - SOL-M Blood Collection Tube 13x75 mm no additive x 4 ml, white cap, sterile
BCTPL002 - SOL-M Blood Collection Tube 13x100 mm no additive x 6 ml, white cap, sterile
BCTPL003 - SOL-M Blood Collection Tube 16x100 mm no additive x 10 ml, white cap, sterile
BCTBU001 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,2 % x 1,8 ml of blood for coagulation, light blue cap, sterile
BCTBU002 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,2 % x 2,7 ml of blood for coagulation, light blue cap, sterile
BCTBU004- SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,2 % x 3,6 ml of blood for coagulation, light blue cap, sterile
BCTBU005 - SOL-M Blood Collection Tube 13x100 mm with Sodium Citrate 3,2 % x 4,5 ml of

blood for coagulation, light blue cap, sterile
 BCTBU003 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,8 % x 1,8 ml of blood for coagulation, light blue cap, sterile
 BCTBU006 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,8 % x 2,7 ml of blood for coagulation, light blue cap, sterile
 BCTBU007 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,8 % x 3,6 ml of blood for coagulation, light blue cap, sterile
 BCTBU008 - SOL-M Blood Collection Tube 13x100 mm with Sodium Citrate 3,8 % x 4,5 ml of blood for coagulation, light blue cap, sterile
 BCTYE001 - SOL-M Blood Collection Tube 13x75 mm with Gel Separator + Clot Activator x 3,5 ml of blood, golden-yellow cap, sterile
 BCTYE002 - SOL-M Blood Collection Tube 13x100 mm with Gel Separator + Clot Activator x 5 ml of blood, golden-yellow cap, sterile
 BCTYE003 - SOL-M Blood Collection Tube 16x100 mm with Gel Separator + Clot Activator x 8.5 ml of blood, golden-yellow cap, sterile
 BCTRD002 - SOL-M Blood Collection Tube 13x100 mm with Clot Activator x 4 ml of blood, red cap, sterile
 BCTRD001- SOL-M Blood Collection Tube 13x100 mm with Clot Activator x 6 ml of blood, red cap, sterile
 BCTRD003 - SOL-M Blood Collection Tube 13x100 mm with Clot Activator x 10 ml of blood, red cap, sterile
 BCTDG001 - SOL-M Blood Collection Tube 13x75 mm with Sodium Heparin x 4 ml of blood, light green cap, sterile
 BCTDG002 - SOL-M Blood Collection Tube 13x100 mm with Sodium Heparin x 6 ml of blood, light green cap, sterile
 BCTDG006 - SOL-M Blood Collection Tube 16x100 mm with Sodium Heparin x 10 ml of blood, light green cap, sterile
 BCTDG003 - SOL-M Blood Collection Tube 13x75 mm with Lithium Heparin x 4 ml of blood, dark green cap, sterile
 BCTDG004 - SOL-M Blood Collection Tube 13x100 mm with Lithium Heparin x 6 ml of blood, dark green cap, sterile
 BCTDG005 - SOL-M Blood Collection Tube 16x100 mm with Lithium Heparin x 10 ml of blood, dark green cap, sterile
 BCTLG001 - SOL-M Blood Collection Tube 13x75 mm with Gel Separator + Lithium Heparin x 3.5 ml of blood, turquoise cap, sterile
 BCTLG002 - SOL-M Blood Collection Tube 13x100 mm with Gel Separator + Lithium Heparin x 4.5 ml of blood, turquoise cap, sterile
 BCTLG003- SOL-M Blood Collection Tube 16x100 mm with Gel Separator + Lithium Heparin x 8 ml of blood, turquoise cap, sterile
 BCTVT009 -SOL-M Blood Collection Tube 13x75 mm with K2 EDTA x 2 ml of blood, lavender cap, sterile
 BCTVT001 - SOL-M Blood Collection Tube 13x75 mm with K2 EDTA x 3 ml of blood, lavender cap, sterile
 BCTVT002- SOL-M Blood Collection Tube 13x75 mm with K2 EDTA x 4 ml of blood, lavender cap, sterile
 BCTVT003 - SOL-M Blood Collection Tube 13x100 mm with K2 EDTA x 6 ml of blood, lavender cap, sterile
 BCTVT008 - SOL-M Blood Collection Tube 16x100 mm with K2 EDTA x 10 ml of blood, lavender cap, sterile
 BCTVT004 - SOL-M Blood Collection Tube 13x75 mm with K3 EDTA x 2 ml of blood, violet cap, sterile

BCTVT005- SOL-M Blood Collection Tube 13x75 mm with K3 EDTA x 3 ml of blood, violet cap, sterile

BCTVT006 - SOL-M Blood Collection Tube 13x75 mm with K3 EDTA x 4 ml of blood, violet cap, sterile

BCTVT007 - SOL-M Blood Collection Tube 13x100 mm with K3 EDTA x 6 ml of blood, violet cap, sterile

BCTVT010 - SOL-M Blood Collection Tube 16x100 mm with K3 EDTA x 10 ml of blood, lavender cap, sterile

BCTWH001 - SOL-M Blood Collection Tube 13x75 mm with Gel Separator + K2/K3 EDTA x 3.5 ml of blood, pearlescent cap, sterile

BCTWH002 - SOL-M Blood Collection Tube 13x100 mm with Gel Separator + K2/K3 EDTA x 5 ml of blood, pearlescent cap, sterile

BCTWH003- SOL-M Blood Collection Tube 16x100 mm with Gel Separator + K2/K3 EDTA x 8,5 ml of blood, pearlescent cap, sterile

BCTBK001 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3.8 % x 1,6 ml of blood for ESR, black cap, sterile

BCTBK002 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3.8 % x 2,4 ml of blood for ESR, black cap, sterile

BCTGY001 - SOL-M Blood Collection Tube 13x75 mm with Sodium Fluoride+EDTA K3 x2ml of blood, grey cap, sterile

BCTGY002 - SOL-M Blood Collection Tube 13x75 mm with Sodium Fluoride+EDTA K3 x3ml of blood, grey cap, sterile

BCTGY003 - SOL-M Blood Collection Tube 13x75 mm with Sodium Fluoride+EDTA K3 x4ml of blood, grey cap, sterile

Presentaciones:

BCTPL001 - SOL-M Blood Collection Tube 13x75 mm no additive x 4 ml, white cap, sterile – Caja x 100.

BCTPL002 - SOL-M Blood Collection Tube 13x100 mm no additive x 6 ml, white cap, sterile – Caja x 100.

BCTPL003 - SOL-M Blood Collection Tube 16x100 mm no additive x 10 ml, white cap, sterile – Caja x 100.

BCTBU001 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,2 % x 1,8 ml of blood for coagulation, light blue cap, sterile – Caja x 100.

BCTBU002 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,2 % x 2,7 ml of blood for coagulation, light blue cap, sterile – Caja x 100.

BCTBU004- SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,2 % x 3,6 ml of blood for coagulation, light blue cap, sterile – Caja x 100.

BCTBU005 - SOL-M Blood Collection Tube 13x100 mm with Sodium Citrate 3,2 % x 4,5 ml of blood for coagulation, light blue cap, sterile – Caja x 100.

BCTBU003 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,8 % x 1,8 ml of blood for coagulation, light blue cap, sterile – Caja x 100.

BCTBU006 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,8 % x 2,7 ml of blood for coagulation, light blue cap, sterile – Caja x 100.

BCTBU007 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3,8 % x 3,6 ml of blood for coagulation, light blue cap, sterile – Caja x 100.

BCTBU008 - SOL-M Blood Collection Tube 13x100 mm with Sodium Citrate 3,8 % x 4,5 ml of blood for coagulation, light blue cap, sterile – Caja x 100.

BCTYE001 - SOL-M Blood Collection Tube 13x75 mm with Gel Separator + Clot Activator x 3,5 ml of blood, golden-yellow cap, sterile– Caja x 100.

BCTYE002 - SOL-M Blood Collection Tube 13x100 mm with Gel Separator + Clot Activator x 5 ml of blood, golden-yellow cap, sterile – Caja x 100.

BCTYE003 - SOL-M Blood Collection Tube 16x100 mm with Gel Separator + Clot Activator x 8.5 ml of blood, golden-yellow cap, sterile – Caja x 100.

BCTRD002 - SOL-M Blood Collection Tube 13x100 mm with Clot Activator x 4 ml of blood, red cap, sterile – Caja x 100.

BCTRD001- SOL-M Blood Collection Tube 13x100 mm with Clot Activator x 6 ml of blood, red cap, sterile – Caja x 100.

BCTRD003 - SOL-M Blood Collection Tube 13x100 mm with Clot Activator x 10 ml of blood, red cap, sterile – Caja x 100.

BCTDG001 - SOL-M Blood Collection Tube 13x75 mm with Sodium Heparin x 4 ml of blood, light green cap, sterile – Caja x 100.

BCTDG002 - SOL-M Blood Collection Tube 13x100 mm with Sodium Heparin x 6 ml of blood, light green cap, sterile – Caja x 100.

BCTDG006 - SOL-M Blood Collection Tube 16x100 mm with Sodium Heparin x 10 ml of blood, light green cap, sterile – Caja x 100.

BCTDG003 - SOL-M Blood Collection Tube 13x75 mm with Lithium Heparin x 4 ml of blood, dark green cap, sterile – Caja x 100.

BCTDG004 - SOL-M Blood Collection Tube 13x100 mm with Lithium Heparin x 6 ml of blood, dark green cap, sterile – Caja x 100.

BCTDG005 - SOL-M Blood Collection Tube 16x100 mm with Lithium Heparin x 10 ml of blood, dark green cap, sterile – Caja x 100.

BCTLG001 - SOL-M Blood Collection Tube 13x75 mm with Gel Separator + Lithium Heparin x 3.5 ml of blood, turquoise cap, sterile– Caja x 100.

BCTLG002 - SOL-M Blood Collection Tube 13x100 mm with Gel Separator + Lithium Heparin x 4.5 ml of blood, turquoise cap, sterile – Caja x 100.

BCTLG003- SOL-M Blood Collection Tube 16x100 mm with Gel Separator + Lithium Heparin x 8 ml of blood, turquoise cap, sterile – Caja x 100.

BCTVT009 -SOL-M Blood Collection Tube 13x75 mm with K2 EDTA x 2 ml of blood, lavender cap, sterile – Caja x 100.

BCTVT001 - SOL-M Blood Collection Tube 13x75 mm with K2 EDTA x 3 ml of blood, lavender cap, sterile – Caja x 100.

BCTVT002- SOL-M Blood Collection Tube 13x75 mm with K2 EDTA x 4 ml of blood, lavender cap, sterile - Caja x 100.

BCTVT003 - SOL-M Blood Collection Tube 13x100 mm with K2 EDTA x 6 ml of blood, lavender cap, sterile- Caja x 100.

BCTVT008 - SOL-M Blood Collection Tube 16x100 mm with K2 EDTA x 10 ml of blood, lavender cap, sterile - Caja x 100.

BCTVT004 - SOL-M Blood Collection Tube 13x75 mm with K3 EDTA x 2 ml of blood, violet cap, sterile - Caja x 100.

BCTVT005- SOL-M Blood Collection Tube 13x75 mm with K3 EDTA x 3 ml of blood, violet cap, sterile - Caja x 100.

BCTVT006 - SOL-M Blood Collection Tube 13x75 mm with K3 EDTA x 4 ml of blood, violet cap, sterile - Caja x 100.

BCTVT007 - SOL-M Blood Collection Tube 13x100 mm with K3 EDTA x 6 ml of blood, violet cap, sterile - Caja x 100.

BCTVT010 - SOL-M Blood Collection Tube 16x100 mm with K3 EDTA x 10 ml of blood, lavender cap, sterile – Caja x 100.

BCTWH001 - SOL-M Blood Collection Tube 13x75 mm with Gel Separator + K2/K3 EDTA x 3.5 ml of blood, pearlescent cap, sterile– Caja x 100.

BCTWH002 - SOL-M Blood Collection Tube 13x100 mm with Gel Separator + K2/K3 EDTA x 5 ml

of blood, pearlescent cap, sterile – Caja x 100.

BCTWH003- SOL-M Blood Collection Tube 16x100 mm with Gel Separator + K2/K3 EDTA x 8,5 ml of blood, pearlescent cap, sterile – Caja x 100.

BCTBK001 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3.8 % x 1,6 ml of blood for ESR, black cap, sterile – Caja x 100.

BCTBK002 - SOL-M Blood Collection Tube 13x75 mm with Sodium Citrate 3.8 % x 2,4 ml of blood for ESR, black cap, sterile – Caja x 100.

BCTGY001 - SOL-M Blood Collection Tube 13x75 mm with Sodium Fluoride+EDTA K3 x2ml of blood, grey cap, sterile – Caja x 100.

BCTGY002 - SOL-M Blood Collection Tube 13x75 mm with Sodium Fluoride+EDTA K3 x3ml of blood, grey cap, sterile– Caja x 100.

BCTGY003 - SOL-M Blood Collection Tube 13x75 mm with Sodium Fluoride+EDTA K3 x4ml of blood, grey cap, sterile– Caja x 100.

Uso previsto:

Los tubos para recolección de sangre están destinados para obtener, contener y conservar muestras de sangre para un examen de diagnóstico in vitro.

Período de vida útil:

16 meses -

Conservar los tubos a una temperatura entre 5° y 30°

Nombre y domicilio del fabricante:

Soyagreentec Co Ltd.

34-26 - Jeyakgongdan 2-gil Hyangnam-eup Hwaseong-si Gyeonggi-do 18622, República de Corea.

Representante

SOL-Millennium Medical Pty Ltd.

Suite 14 26-30, Tedder Avenue, Main Beach QLD 4217, Australia

Categoría:

Uso profesional exclusivo

LUGAR Y FECHA: Argentina, 08 octubre 2025

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Sofia

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FAVORITO Ana Clara
CUIL 27297934770

Responsable Técnico
Firma y Sello



Ministerio de Salud
Secretaria de Calidad en Salud
A.N.M.A.T.

La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 2198/22, quedando autorizada la comercialización del/los producto/s identificados en la misma.

Inscripta en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) bajo el número PM **1680-46**

Se autoriza la comercialización del/los producto/s identificados en la presente declaración de conformidad en la Ciudad de Buenos Aires a los días 08 octubre 2025 la cual tendrá una vigencia de cinco (5) años a contar de la fecha.



BODNAR Andrea Veronica
CUIL 27254978472

Dirección de Evaluación de Registro
Firma y Sello



TERRIZZANO Maria Lorena
CUIL 23242965604

Instituto Nacional de Productos Médicos
Firma y Sello



La validez del presente documento deberá verificarse mediante el código QR.

Tramitada por Expediente N°: 1-0047-3110-003394-25-4



SCHIUMA Cecilia Constanza
CUIL 23275362964