

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	AGUJAS PARA TATUAJE – TATTOO NEEDLES
NO. IDENTIFICACIÓN RISARH	R1407-304
REFERENCIAS DEL DISPOSITIVO MEDICO	1203RL, 1205m, 1205RL, 1205RS, 1209RL, 1207RL, 1207m, 1207RS, 1209m y 1209RS con lotes 201307, 201308, 201310, 201311, 201312, 201402 y fecha de vencimiento JUN 2018. Esterilizadas por Oxido de Etileno (OE)
REGISTRO SANITARIO	Sin Registro Sanitario Otorgado
INDICACIONES Y USO ESTABLECIDOS	Agujas para tatuaje
NOMBRE DEL FABRICANTE	White & Blue Lion, Inc. (Importador para los Estados Unidos)
DESCRIPCION DEL PROBLEMA	La .FDA informa que ha detectado que el dispositivo medico en mención fue expuesto a contaminación bacteriana patógena, conllevando a que se generen posibles infecciones bacterianas y sepsis, complicación potencialmente mortal de una infección.
FUENTE	http://www.fda.gov/Safety/Recalls/ucm404787.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
FECHA DE NOTIFICACION	23 de Julio de 2014

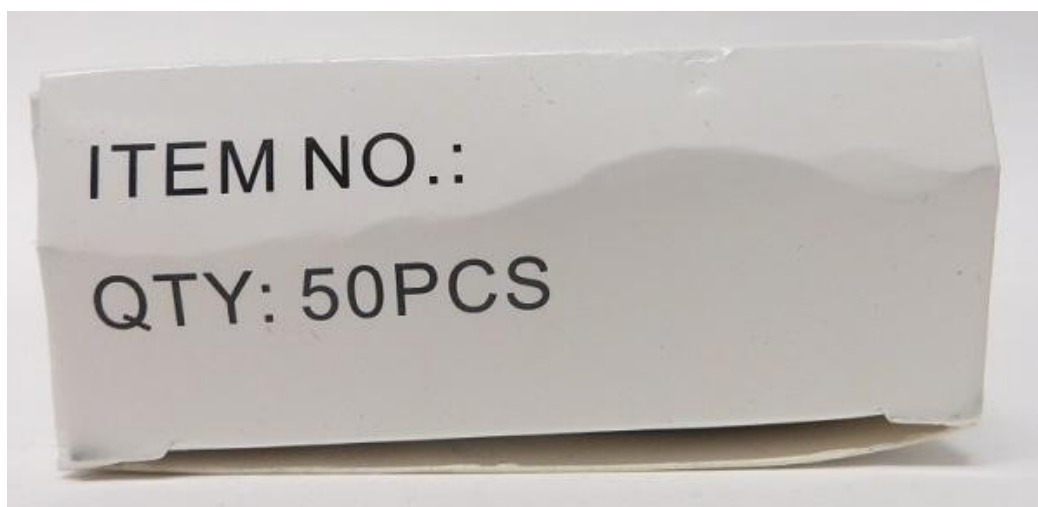
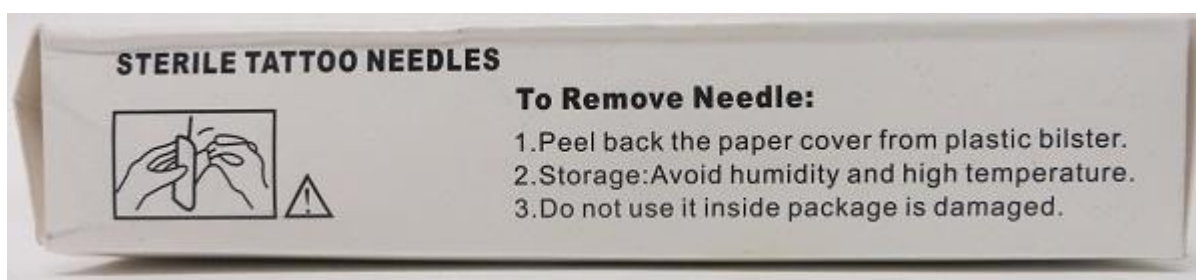
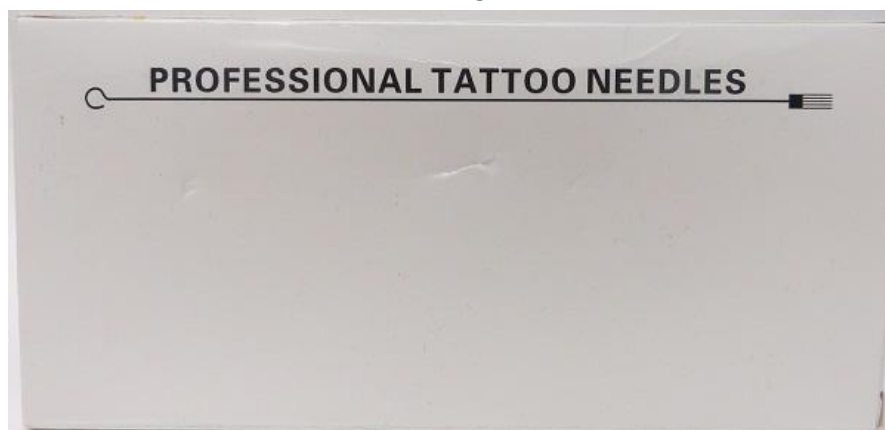
RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con la secretaria de salud de su municipio o departamento quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

ANEXO 1



CE 0197	Pre-made tattoo needle	This needle was sterilized by E.O.Gas	Art No. 1205RS	Lot No. 201312	Expire on JUN2018
CE 0197	Pre-made tattoo needle	This needle was sterilized by E.O.Gas	Art No. 1205RS	Lot No. 201312	Expire on JUN2018
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CE 0197	Pre-made tattoo needle	This needle was sterilized by E.O.Gas	Art No. 1209M	Lot No. 201310	Expire on JUN2018
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CE 0197	Pre-made tattoo needle	This needle was sterilized by E.O.Gas	Art No. 1207RS	Lot No. 201311	Expire on JUN2018
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CE 0197	Pre-made tattoo needle	This needle was sterilized by E.O.Gas	Art No. 1209RL	Lot No. 201312	Expire on JUN2018
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CE 0197	Pre-made tattoo needle	This needle was sterilized by E.O.Gas	Art No. 1207RL	Lot No. 201402	Expire on JUN2019
CE 0197	Pre-made tattoo needle	This needle was sterilized by E.O.Gas	Art No. 1207RL	Lot No. 201402	Expire on JUN2019
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