



**Ministerio de Salud**  
República Argentina

2026 - AÑO DE LA GRANDEZA ARGENTINA

## **DECLARACION JURADA**

DISPOSICIÓN ANMAT N° 236/2026  
DECRETO 895/25

**N° rev: 2769-14#0001**

En nombre y representación de la firma HECA GLOBAL S.A. , el responsable legal y el responsable técnico declaran bajo juramento cumplir con la Disposición 236/26 para el producto médico declarado bajo el Número de PM: 2769-14

### **Datos Característicos del Producto Médico:**

Nombre descriptivo: Agujas descartables de radiofrecuencia (RF)

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):  
15-579 Electrodo, para Electrocirugía

Marca(s) de (los) producto(s) médico(s): Spectra

Regla de clasificación Disposición ANMAT N° 64/25: Regla 6

Clase de Riesgo: II

Indicación/es de uso: Procedimientos de ablación térmica por radiofrecuencia para el alivio del dolor

Modelos: SST181005NC Sharp Straight Radiofrequency Needle 18ga x 10cm x 5mm, SST181010NC Sharp Straight Radiofrequency Needle 18ga x 10cm x 10mm, SST181505NC Sharp Straight Radiofrequency Needle 18ga x 15cm x 5mm, SST181510NC Sharp Straight Radiofrequency Needle 18ga x 15cm x 10mm, SST200505NC Sharp Straight Radiofrequency Needle 20ga x 5cm x 5mm, SST201005NC Sharp Straight Radiofrequency Needle 20ga x 10cm x 5mm, SST201010NC Sharp Straight Radiofrequency Needle 20ga x 10cm x 10mm, SST201505NC Sharp Straight Radiofrequency Needle 20ga x 15cm x 5mm, SST201510NC Sharp Straight Radiofrequency Needle 20ga x 15cm x 10mm, SST201515NC Sharp Straight Radiofrequency Needle 20ga x 15cm x 15mm, SST201520NC Sharp Straight Radiofrequency Needle 20ga x 15cm x 20mm, SST210504NC Sharp Straight Radiofrequency Needle 21ga x 5cm x 4mm, SST210510NC Sharp Straight Radiofrequency Needle 21ga x 5cm x 10mm,

SST211005NC Sharp Straight Radiofrequency Needle 21ga x 10cm x 5mm, SST211010NC Sharp Straight Radiofrequency Needle 21ga x 10cm x 10mm, SST220504NC Sharp Straight Radiofrequency Needle 22ga x 5cm x 4mm, SST220505NC Sharp Straight Radiofrequency Needle 22ga x 5cm x 5mm, SST220510NC Sharp Straight Radiofrequency Needle 22ga x 5cm x 10mm, SST221005NC Sharp Straight Radiofrequency Needle 22ga x 10cm x 5mm, SST221010NC Sharp Straight Radiofrequency Needle 22ga x 10cm x 10mm, SCV160506NC Sharp Curved Radiofrequency Needle 16ga x 5cm x 6mm, SCV160510NC Sharp Curved Radiofrequency Needle 16ga x 5cm x 10mm, SCV161010NC Sharp Curved Radiofrequency Needle 16ga x 10cm x 10mm, SCV161510NC Sharp Curved Radiofrequency Needle 16ga x 15cm x 10mm, SCV180505NC Sharp Curved Radiofrequency Needle 18ga x 5cm x 5mm, SCV181005NC Sharp Curved Radiofrequency Needle 18ga x 10cm x 5mm, SCV181010NC Sharp Curved Radiofrequency Needle 18ga x 10cm x 10mm, SCV181505NC Sharp Curved Radiofrequency Needle 18ga x 15cm x 5mm, SCV181510NC Sharp Curved Radiofrequency Needle 18ga x 15cm x 10mm, SCV200505NC Sharp Curved Radiofrequency Needle 20ga x 5cm x 5mm, SCV200510NC Sharp Curved Radiofrequency Needle 20ga x 5cm x 10mm, SCV201005NC Sharp Curved Radiofrequency Needle 20ga x 10cm x 5mm, SCV201010NC Sharp Curved Radiofrequency Needle 20ga x 10cm x 10mm, SCV201505NC Sharp Curved Radiofrequency Needle 20ga x 15cm x 5mm, SCV201510NC Sharp Curved Radiofrequency Needle 20ga x 15cm x 10mm, SCV201515NC Sharp Curved Radiofrequency Needle 20ga x 15cm x 15mm, SCV220504NC Sharp Curved Radiofrequency Needle 22ga x 5cm x 4mm, SCV220505NC Sharp Curved Radiofrequency Needle 22ga x 5cm x 5mm, SCV220510NC Sharp Curved Radiofrequency Needle 22ga x 5cm x 10mm, SCV221005NC Sharp Curved Radiofrequency Needle 22ga x 10cm x 5mm, SCV221010NC Sharp Curved Radiofrequency Needle 22ga x 10cm x 10mm, SBC201005NC Blunt Curved Radiofrequency Needle 20ga x 10cm x 5mm, SBC201010NC Blunt Curved Radiofrequency Needle 20ga x 10cm x 10mm, SBC201505NC Blunt Curved Radiofrequency Needle 20ga x 15cm x 5mm, SBC201510NC Blunt Curved Radiofrequency Needle 20ga x 15cm x 10mm, SCV180505SL Sharp Curved Radiofrequency Needle 18ga x 5cm x 5mm, SCV181005SL Sharp Curved Radiofrequency Needle 18ga x 10cm x 5mm, SCV181010SL Sharp Curved Radiofrequency Needle 18ga x 10cm x 10mm, SCV181505SL Sharp Curved Radiofrequency Needle 18ga x 15cm x 5mm, SCV181510SL Sharp Curved Radiofrequency Needle 18ga x 15cm x 10mm, SCV200505SL Sharp Curved Radiofrequency Needle 20ga x 5cm x 5mm, SCV200510SL Sharp Curved Radiofrequency Needle 20ga x 5cm x 10mm, SCV201005SL Sharp Curved Radiofrequency Needle 20ga x 10cm x 5mm, SCV201010SL Sharp Curved Radiofrequency Needle 20ga x 10cm x 10mm, SCV201505SL Sharp Curved Radiofrequency Needle 20ga x 15cm x 5mm, SCV201510SL Sharp Curved Radiofrequency Needle 20ga x 15cm x 10mm, SCV220505SL Sharp Curved Radiofrequency Needle 22ga x 5cm x 5mm, SCV220510SL Sharp Curved Radiofrequency Needle 22ga x 5cm x 10mm, SCV221005SL Sharp Curved Radiofrequency Needle 22ga x 10cm x 5mm, SCV221010SL Sharp Curved Radiofrequency Needle 22ga x 10cm x 10mm, SST180505SL Sharp Straight Radiofrequency Needle 18ga x 5cm x 5mm, SST181005SL Sharp Straight Radiofrequency Needle 18ga x 10cm x 5mm, SST181010SL Sharp Straight Radiofrequency Needle 18ga x 10cm x 10mm, SST181505SL Sharp Straight Radiofrequency Needle 18ga x 15cm x 5mm, SST201005SL Sharp Straight Radiofrequency Needle 20ga x 10cm x 5mm, SST201010SL Sharp Straight Radiofrequency Needle 20ga x 10cm x 10mm, SST201505SL Sharp Straight Radiofrequency Needle 20ga x 15cm x 5mm, SST201510SL Sharp Straight Radiofrequency Needle 20ga x 15cm x 10mm, SST211005SL Sharp Straight Radiofrequency Needle 21ga x 10cm x 5mm, SST211010SL Sharp Straight Radiofrequency Needle 21ga x 10cm x 10mm, SST220504SL Sharp Straight Radiofrequency Needle 22ga x 5cm x 4mm, SST220505SL Sharp Straight Radiofrequency Needle 22ga x 5cm x 5mm, SST220510SL Sharp Straight Radiofrequency Needle 22ga x 5cm x 10mm, SST221005SL Sharp Straight Radiofrequency Needle 22ga x 10cm x 5mm, SST221010SL Sharp Straight

Radiofrequency Needle 22ga x 10cm x 10mm, SST221505SL Sharp Straight Radiofrequency Needle 22ga x 15cm x 5mm, SST201005EC Sharp Straight Radiofrequency Needle 20ga x 10cm x 5mm, SST201010EC Sharp Straight Radiofrequency Needle 20ga x 10cm x 10mm, SST201505EC Sharp Straight Radiofrequency Needle 20ga x 15cm x 5mm, SST201510EC Sharp Straight Radiofrequency Needle 20ga x 15cm x 10mm, SST210505EC Sharp Straight Radiofrequency Needle 21ga x 5cm x 5mm, SST210510EC Sharp Straight Radiofrequency Needle 21ga x 5cm x 10mm, SST211010EC Sharp Straight Radiofrequency Needle 21ga x 10cm x 10mm, SST221005EC Sharp Straight Radiofrequency Needle 22ga x 10cm x 5mm, SST221510EC Sharp Straight Radiofrequency Needle 22ga x 15cm x 10mm,

Composición cuali-cuanti porcentual exacta (si corresponde): No Aplica

Período de vida útil: 5 Años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Contiene látex: NO

Forma de presentación: Caja por 1-8-25-200

Método de esterilización: EtO

Condición de conservación/almacenamiento (SI CORRESPONDE): No Aplica

Nombre del fabricante: 1\_ SPECTRA MEDICAL DEVICES, LLC, 2\_ CUSTOM TUBE MANUFACTURING LLC

Lugar de elaboración: 1\_ 299 Ballardvale St Ste 1 WILMINGTON, MA Estados unidos 01887, 2\_ 38-4, Hyeonseok-ro 733 beon-gil Gwangjeok-myeon Yangku-si, Gyeonggi Republica de Corea 11413

El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento que el producto médico , que cumple y satisface con los Requisitos Esenciales de Seguridad y Desempeño (R.E.S.D.) previstos por la Disposición ANMAT N° 11467/24.

La empresa mantiene en su establecimiento y a disposición de la autoridad sanitaria la documentación requerida por Disposición ANMAT N°236/26, Disposición ANMAT N°64/25 y Disposición ANMAT N° 9688/19.

Firma del Responsable Legal

Firme Responsable Técnico

La presente DECLARACIÓN JURADA ha sido emitida de acuerdo con las previsiones del Decreto 892/25 y la Disposición ANMAT N° 236/26, quedando en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de HECA GLOBAL S.A. bajo el número PM 2769-14, siendo su vigencia hasta el 28 julio de 2031

La presente DJ será válida cuando sea escaneado su código QR y verificada digitalmente a través de la página de ANMAT. Asimismo, deberá estar acompañada de las disposiciones o DJ de habilitación enunciadas anteriormente.



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

N° Identificadorio Trámite: 80147

Tramitada por Expediente N°: 1-0047-3110-005689-26-9