



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

**CERTIFICADO DE AUTORIZACIÓN DE MODIFICACIÓN**

**N° rev: 1991-141#0004**

El Instituto Nacional de Productos Médicos de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por MTG GROUP S.R.L. , se autoriza la modificación en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM), del PM 1991-141 aprobado según:

Disposición autorizante N° 9953/17 de fecha 14 septiembre 2017

Disposiciones modificatorias y reválidas N°: Declaración de Conformidad de Modificación (2017), Expediente 1-47-3110-7281-17-1

Declaración de Conformidad de Modificación rev 1991-141#0001, Expediente 1-47-3110-1132-22-0

Certificado de autorización de Modificación rev 1991-141#0002, Expediente 1-47-3110-6048-22-3

Declaración Jurada de Revalida rev 1991-141#0002, Expediente 1-47-3110-5138-22-8

Certificado de Autorización de Modificación rev 1991-141#0003, Expediente 1-47-3110-4271-23-1

Del siguiente/s dato/s característico/s:

| DATO IDENTIFICATORIO A MODIFICAR | DATO AUTORIZADO HASTA LA FECHA                                                                                                                                                                                                             | MODIFICACION/RECTIFICACION AUTORIZADA                                                                                                                             |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Modelos                          | COVERATM<br>AVFLE06040 Covera 8F<br>6/40/1200mm F OUS<br>AVFLE06060 Covera 8F<br>6/60/1200mm F OUS<br>AVFLE06080 Covera 8F<br>6/80/1200mm F OUS<br>AVFLE06100 Covera 8F<br>6/100/1200mm F OUS<br>AVFLE07040 Covera 8F<br>7/40/1200mm F OUS | STENT VASCULAR RECUBIERTO<br>COVERA<br>AVFLE06040<br>AVFLE06060<br>AVFLE06080<br>AVFLE06100<br>AVFLE07040<br>AVFLE07060<br>AVFLE07080<br>AVFLE07100<br>AVFLE08040 |

|                      |            |
|----------------------|------------|
| AVFLE07060 Covera 8F | AVFLE08060 |
| 7/60/1200mm F OUS    | AVFLE08080 |
| AVFLE07080 Covera 8F | AVFLE08100 |
| 7/80/1200mm F OUS    | AVFLE09040 |
| AVFLE07100 Covera 8F | AVFLE09060 |
| 7/100/1200mm F OUS   | AVFLE09080 |
| AVFLE08040 Covera 8F | AVFLE09100 |
| 8/40/1200mm F OUS    | AVFLE10040 |
| AVFLE08060 Covera 8F | AVFLE10060 |
| 8/60/1200mm F OUS    | AVFLE10080 |
| AVFLE08080 Covera 8F | AVFLE10100 |
| 8/80/1200mm F OUS    | AVFME06040 |
| AVFLE08100 Covera 9F | AVFME06060 |
| 8/100/1200mm F OUS   | AVFME06080 |
| AVFLE09040 Covera 8F | AVFME06100 |
| 9/40/1200mm F OUS    | AVFME07040 |
| AVFLE09060 Covera 8F | AVFME07060 |
| 9/60/1200mm F OUS    | AVFME07080 |
| AVFLE09080 Covera 8F | AVFME07100 |
| 9/80/1200mm F OUS    | AVFME08040 |
| AVFLE09100 Covera 9F | AVFME08060 |
| 9/100/1200mm F OUS   | AVFME08080 |
| AVFLE10040 Covera 8F | AVFME08100 |
| 10/40/1200mm F OUS   | AVFME09040 |
| AVFLE10060 Covera 8F | AVFME09060 |
| 10/60/1200mm F OUS   | AVFME09080 |
| AVFLE10080 Covera 9F | AVFME09100 |
| 10/80/1200mm F OUS   | AVFME10040 |
| AVFLE10100 Covera 9F | AVFME10060 |
| 10/100/1200mm F OUS  | AVFME10080 |
| AVFME06040 Covera 8F | AVFME10100 |
| 6/40/800mm F OUS     | AVSLE06030 |
| AVFME06060 Covera 8F | AVSLE06040 |
| 6/60/800mm F OUS     | AVSLE06060 |
| AVFME06080 Covera 8F | AVSLE06080 |
| 6/80/800mm F OUS     | AVSLE06100 |
| AVFME06100 Covera 8F | AVSLE07030 |
| 6/100/800mm F OUS    | AVSLE07040 |
| AVFME07040 Covera 8F | AVSLE07060 |
| 7/40/800mm F OUS     | AVSLE07080 |
| AVFME07060 Covera 8F | AVSLE07100 |
| 7/60/800mm F OUS     | AVSLE08030 |
| AVFME07080 Covera 8F | AVSLE08040 |
| 7/80/800mm F OUS     | AVSLE08060 |
| AVFME07100 Covera 8F | AVSLE08080 |
| 7/100/800mm F OUS    | AVSLE08100 |
| AVFME08040 Covera 8F | AVSLE09030 |
| 8/40/800mm F OUS     | AVSLE09040 |
| AVFME08060 Covera 8F | AVSLE09060 |
| 8/60/800mm F OUS     | AVSLE09080 |

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|--------------------------------------------|-------------------------------------------|
| AVFME08080 Covera 8F<br>8/80/800mm F OUS   | AVSLE09100<br>AVSLE10030                  |
| AVFME08100 Covera 9F<br>8/100/800mm F OUS  | AVSLE10040<br>AVSLE10060                  |
| AVFME09040 Covera 8F<br>9/40/800mm F OUS   | AVSLE10080<br>AVSLE10100                  |
| AVFME09060 Covera 8F<br>9/60/800mm F OUS   | AVSME06030<br>AVSME06040                  |
| AVFME09080 Covera 8F<br>9/80/800mm F OUS   | AVSME06060<br>AVSME06080                  |
| AVFME09100 Covera 9F<br>9/100/800mm F OUS  | AVSME06100<br>AVSME07030                  |
| AVFME10040 Covera 8F<br>10/40/800mm F OUS  | AVSME07040<br>AVSME07060                  |
| AVFME10060 Covera 8F<br>10/60/800mm F OUS  | AVSME07080<br>AVSME07100                  |
| AVFME10080 Covera 9F<br>10/80/800mm F OUS  | AVSME08030<br>AVSME08040                  |
| AVFME10100 Covera 9F<br>10/100/800mm F OUS | AVSME08060<br>AVSME08080                  |
| AVSLE06030 Covera 8F<br>6/30/1200mm S OUS  | AVSME08100<br>AVSME09030                  |
| AVSLE06040 Covera 8F<br>6/40/1200mm S OUS  | AVSME09040<br>AVSME09060                  |
| AVSLE06060 Covera 8F<br>6/60/1200mm S OUS  | AVSME09080<br>AVSME09100                  |
| AVSLE06080 Covera 8F<br>6/80/1200mm S OUS  | AVSME10030<br>AVSME10040                  |
| AVSLE06100 Covera 8F<br>6/100/1200mm S OUS | AVSME10060<br>AVSME10080                  |
| AVSLE07030 Covera 8F<br>7/30/1200mm S OUS  | AVSME10100                                |
| AVSLE07040 Covera 8F<br>7/40/1200mm S OUS  | STENT VASCULAR RECUBIERTO<br>COVERA PLUS: |
| AVSLE07060 Covera 8F<br>7/60/1200mm S OUS  | AASME06030<br>AASME06040                  |
| AVSLE07080 Covera 8F<br>7/80/1200mm S OUS  | AASME06060<br>AASME06080                  |
| AVSLE07100 Covera 8F<br>7/100/1200mm S OUS | AASME06100<br>AASME07030                  |
| AVSLE08030 Covera 8F<br>8/30/1200mm S OUS  | AASME07040<br>AASME07060                  |
| AVSLE08040 Covera 8F<br>8/40/1200mm S OUS  | AASME07080<br>AASME07100                  |
| AVSLE08060 Covera 8F<br>8/60/1200mm S OUS  | AASME08030<br>AASME08040                  |
| AVSLE08080 Covera 8F<br>8/80/1200mm S OUS  | AASME08060<br>AASME08080                  |
| AVSLE08100 Covera 9F<br>8/100/1200mm S OUS | AASME08100<br>AASME09030                  |

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| AVSLE09030 Covera 8F<br>9/30/1200mm S OUS   |            |
| AVSLE09040 Covera 8F<br>9/40/1200mm S OUS   |            |
| AVSLE09060 Covera 8F<br>9/60/1200mm S OUS   |            |
| AVSLE09080 Covera 8F<br>9/80/1200mm S OUS   |            |
| AVSLE09100 Covera 9F<br>9/100/1200mm S OUS  | AASME09040 |
| AVSLE10030 Covera 8F<br>10/30/1200mm S OUS  | AASME09060 |
| AVSLE10040 Covera 8F<br>10/40/1200mm S OUS  | AASME09080 |
| AVSLE10060 Covera 8F<br>10/60/1200mm S OUS  | AASME09100 |
| AVSLE10080 Covera 8F<br>10/80/1200mm S OUS  | AASME10030 |
| AVSLE10100 Covera 8F<br>10/100/1200mm S OUS | AASME10040 |
| AVSME06030 Covera 8F<br>6/30/800mm S OUS    | AASME10060 |
| AVSME06040 Covera 8F<br>6/40/800mm S OUS    | AASME10080 |
| AVSME06060 Covera 8F<br>6/60/800mm S OUS    | AASME10100 |
| AVSME06080 Covera 8F<br>6/80/800mm S OUS    | AASLE06030 |
| AVSME06100 Covera 8F<br>6/100/800mm S OUS   | AASLE06040 |
| AVSME07030 Covera 8F<br>7/30/800mm S OUS    | AASLE06060 |
| AVSME07040 Covera 8F<br>7/40/800mm S OUS    | AASLE06080 |
| AVSME07060 Covera 8F<br>7/60/800mm S OUS    | AASLE06100 |
| AVSME07080 Covera 8F<br>7/80/800mm S OUS    | AASLE07030 |
| AVSME07100 Covera 8F<br>7/100/800mm S OUS   | AASLE07040 |
| AVSME08030 Covera 8F<br>8/30/800mm S OUS    | AASLE07060 |
| AVSME08040 Covera 8F<br>8/40/800mm S OUS    | AASLE07080 |
| AVSME08060 Covera 8F<br>8/60/800mm S OUS    | AASLE07100 |
| AVSME08080 Covera 8F<br>8/80/800mm S OUS    | AASLE08030 |
| AVSME08100 Covera 9F<br>8/100/800mm S OUS   | AASLE08040 |
|                                             | AASLE08060 |
|                                             | AASLE08080 |
|                                             | AASLE08100 |
|                                             | AASLE09030 |
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|                                             | AASLE09100 |
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|                                             | AASLE10080 |
|                                             | AASLE10100 |



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|  | <p>AVSME09030 Covera 8F<br/>9/30/800mm S OUS</p> <p>AVSME09040 Covera 8F<br/>9/40/800mm S OUS</p> <p>AVSME09060 Covera 8F<br/>9/60/800mm S OUS</p> <p>AVSME09080 Covera 8F<br/>9/80/800mm S OUS</p> <p>AVSME09100 Covera 9F<br/>9/100/800mm S OUS</p> <p>AVSME10030 Covera 8F<br/>10/30/800mm S OUS</p> <p>AVSME10040 Covera 8F<br/>10/40/800mm S OUS</p> <p>AVSME10060 Covera 8F<br/>10/60/800mm S OUS</p> <p>AVSME10080 Covera 9F<br/>10/80/800mm S OUS</p> <p>AVSME10100 Covera 9F<br/>10/100/800mm S OUS</p> <p>COVERA PLUS:</p> <p>AASME06030 Covera P 8F<br/>6/30/800mm S OUS</p> <p>AASME06040 Covera P 8F<br/>6/40/800mm S OUS</p> <p>AASME06060 Covera P 8F<br/>6/60/800mm S OUS</p> <p>AASME06080 Covera P 8F<br/>6/80/800mm S OUS</p> <p>AASME06100 Covera P 8F<br/>6/100/800mm S OUS</p> <p>AASME07030 Covera P 8F<br/>7/30/800mm S OUS</p> <p>AASME07040 Covera P 8F<br/>7/40/800mm S OUS</p> <p>AASME07060 Covera P 8F<br/>7/60/800mm S OUS</p> <p>AASME07080 Covera P 8F<br/>7/80/800mm S OUS</p> <p>AASME07100 Covera P 8F<br/>7/100/800mm S OUS</p> <p>AASME08030 Covera P 8F<br/>8/30/800mm S OUS</p> <p>AASME08040 Covera P 8F<br/>8/40/800mm S OUS</p> <p>AASME08060 Covera P 8F<br/>8/60/800mm S OUS</p> <p>AASME08080 Covera P 8F</p> |  |
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|  | 8/80/800mm S OUS       |  |
|  | AASME08100 Covera P 9F |  |
|  | 8/100/800mm S OUS      |  |
|  | AASME09030 Covera P 8F |  |
|  | 9/30/800mm S OUS       |  |
|  | AASME09040 Covera P 8F |  |
|  | 9/40/800mm S OUS       |  |
|  | AASME09060 Covera P 8F |  |
|  | 9/60/800mm S OUS       |  |
|  | AASME09080 Covera P 8F |  |
|  | 9/80/800mm S OUS       |  |
|  | AASME09100 Covera P 9F |  |
|  | 9/100/800mm S OUS      |  |
|  | AASME10030 Covera P 8F |  |
|  | 10/30/800mm S OUS      |  |
|  | AASME10040 Covera P 8F |  |
|  | 10/40/800mm S OUS      |  |
|  | AASME10060 Covera P 8F |  |
|  | 10/60/800mm S OUS      |  |
|  | AASME10080 Covera P 9F |  |
|  | 10/80/800mm S OUS      |  |
|  | AASME10100 Covera P 9F |  |
|  | 10/100/800mm S OUS     |  |
|  | AASLE06030 Covera P 8F |  |
|  | 6/30/1200mm S OUS      |  |
|  | AASLE06040 Covera P 8F |  |
|  | 6/40/1200mm S OUS      |  |
|  | AASLE06060 Covera P 8F |  |
|  | 6/60/1200mm S OUS      |  |
|  | AASLE06080 Covera P 8F |  |
|  | 6/80/1200mm S OUS      |  |
|  | AASLE06100 Covera P 8F |  |
|  | 6/100/1200mm S OUS     |  |
|  | AASLE07030 Covera P 8F |  |
|  | 7/30/1200mm S OUS      |  |
|  | AASLE07040 Covera P 8F |  |
|  | 7/40/1200mm S OUS      |  |
|  | AASLE07060 Covera P 8F |  |
|  | 7/60/1200mm S OUS      |  |
|  | AASLE07080 Covera P 8F |  |
|  | 7/80/1200mm S OUS      |  |
|  | AASLE07100 Covera P 8F |  |
|  | 7/100/1200mm S OUS     |  |
|  | AASLE08030 Covera P 8F |  |
|  | 8/30/1200mm S OUS      |  |
|  | AASLE08040 Covera P 8F |  |
|  | 8/40/1200mm S OUS      |  |
|  | AASLE08060 Covera P 8F |  |
|  | 8/60/1200mm S OUS      |  |
|  | AASLE08080 Covera P 8F |  |

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|  | 8/80/1200mm S OUS<br>AASLE08100 Covera P 9F<br>8/100/1200mm S OUS<br>AASLE09030 Covera P 8F<br>9/30/1200mm S OUS<br>AASLE09040 Covera P 8F<br>9/40/1200mm S OUS<br>AASLE09060 Covera P 8F<br>9/60/1200mm S OUS<br>AASLE09100 Covera P 9F<br>9/100/1200mm S OUS<br>AASLE10030 Covera P 8F<br>10/30/1200mm S OUS<br>AASLE10040 Covera P 8F<br>10/40/1200mm S OUS<br>AASLE10060 Covera P 8F<br>10/60/1200mm S OUS<br>AASLE10080 Covera P 9F<br>10/80/1200mm S OUS<br>AASLE10100 Covera P 9F<br>10/100/1200mm S OUS |  |
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Quedando el producto inscripto con los siguientes datos característicos:

Nombre descriptivo: STENT VASCULAR RECUBIERTO PERIFERICO

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):  
18-238 Endoprótesis (Stents), vasculares periféricos

Marca(s) de (los) producto(s) médico(s): Covera™

Clase de Riesgo: III

Indicación/es autorizada/s: El Stent vascular recubierto Covera y Covera Plus están indicados para su uso en pacientes en hemodiálisis para el tratamiento de estenosis en el flujo venoso eferente de una fístula arteriovenosa (AV) y en la anastomosis venosa de un injerto AV sintético de ePTFE u otros materiales. Además, el stent vascular recubierto Covera Plus está indicado para el tratamiento de lesiones ateroscleróticas en la arteria ilíaca común y externa.

Modelos: STENT VASCULAR RECUBIERTO COVERA

AVFLE06040  
AVFLE06060  
AVFLE06080  
AVFLE06100  
AVFLE07040  
AVFLE07060  
AVFLE07080  
AVFLE07100  
AVFLE08040  
AVFLE08060  
AVFLE08080  
AVFLE08100  
AVFLE09040

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AVFLE09080  
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AVFLE10080  
AVFLE10100  
AVFME06040  
AVFME06060  
AVFME06080  
AVFME06100  
AVFME07040  
AVFME07060  
AVFME07080  
AVFME07100  
AVFME08040  
AVFME08060  
AVFME08080  
AVFME08100  
AVFME09040  
AVFME09060  
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AVFME10080  
AVFME10100  
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AVSLE10080

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AVSME09080  
AVSME09100  
AVSME10030  
AVSME10040  
AVSME10060  
AVSME10080  
AVSME10100

STENT VASCULAR RECUBIERTO COVERA PLUS:

AASME06030  
AASME06040  
AASME06060  
AASME06080  
AASME06100  
AASME07030  
AASME07040  
AASME07060  
AASME07080  
AASME07100  
AASME08030  
AASME08040  
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AASME10060

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AASLE06030  
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AASLE07030  
AASLE07040  
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AASLE10080  
AASLE10100

Período de vida útil: 2 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biotecnológico: N/A

Forma de presentación: POR UNIDAD

Método de esterilización: OXIDO DE ETILENO

Nombre del fabricante: Angiomed GmbH & Co. Medizintechnik KG

Lugar de elaboración: Wachhausstrasse 6, 76227 Karlsruhe, Alemania

### **AUTORIZADO**

Habiéndose cumplimentado con lo previsto en la Disposición ANMAT N° 2318/02 y 9688/19, esta Administración autoriza las modificaciones solicitadas en Argentina, Ciudad de Buenos Aires, 29 mayo 2024.



|                                                                                                                                                                                                                                                              |                                                                                                                                                                                                    |
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| <br>BODNAR Andrea Veronica<br>CUIL 27254978472<br>Dirección Evaluación y Registro de Productos<br>Médicos<br>Firma y Sello                                                  | <br>GARCIA Maria Andrea<br>Instituto Nacional de Productos Médicos<br>CUIL 27247738822<br>ANMAT<br>Firma y Sello |
| El presente certificado será válido únicamente cuando se presente junto con las Disposiciones previas del PM enunciadas anteriormente y sea verificado con su código QR a través de la página de ANMAT. Este certificado no modifica el período de vigencia. |                                                                                                                                                                                                    |
| Fecha de emisión: 29 mayo 2024                                                                                                                                                                                                                               |                                                                                                                                                                                                    |
|                                                                                                                                                                           |                                                                                                                                                                                                    |
| La validez del presente documento deberá verificarse mediante el código QR.                                                                                                                                                                                  |                                                                                                                                                                                                    |
| N° Identificadorio Trámite: 56722                                                                                                                                                                                                                            |                                                                                                                                                                                                    |

  
ABRIOLA Leticia Adriana  
CUIL 27323186494