

Sistema de Aférese AmiCORE

Notas da versão do software

SW v. 2.1

REF

6R8800
6R8800BR

MD

Notas da versão 2.1 do software AmiCORE

Introdução

Este documento fornece notas da versão 2.1 do Sistema de Aférese AmiCORE. Ele fornece conteúdo complementar para o Manual do Operador do Sistema de Aférese AmiCORE e ao Guia do Administrador que são específicos para esta versão de software.

Visão geral desta versão

A versão 2.1.82.735 do Sistema de Aférese AmiCORE incluiu os seguintes recursos:

- Melhorias de desempenho no ciclo de reinjeção final para otimizar o tempo do procedimento.
- Opção de perfusão de solução salina adicional durante o ciclo final de reinjeção.
- Adição de uma verificação secundária para o posicionamento correto das linhas de retirada e retorno após a retomada de uma sobreposição do alerta 2105.
- Adição de um segundo conjunto de configurações padrão para as principais configurações do procedimento.
- Suporte aos novos códigos de kit descartáveis 7R AmiCORE.
- Adição dos idiomas norueguês e português do Brasil.
- Capacidade de acessar o Estimator de doação sem iniciar um novo procedimento.
- Atualizações ao temporizador de desinfecção para incluir fases de retardo, desinfecção e secagem.
- Otimizações para reduzir a variação do rendimento de plaquetas devido a interrupções e alterações na taxa de fluxo do doador.
- Otimizações para o algoritmo de controle de fluxo inteligente.
- Opção de aplicar um rótulo à bolsa de plasma concomitante após a punção venosa sem disparar um alerta de balança.
- Notificações mais rápidas para condições de bloqueio da linha da centrífuga.

- Melhorias contínuas para reduzir os alertas e condições de desequilíbrio da bolsa, reduzir o tempo de preparação e procedimento e otimizar a usabilidade do operador.
- Adição de fusos horários para a Austrália e a Nova Zelândia.
- Metodologia de autenticação atualizada para a conexão com um sistema de gerenciamento de dados.
- Melhorias nos cálculos residuais do plasma, inclusive no caso de um cenário de falta de energia.
- Possibilidade de pausar o procedimento diretamente a partir de uma sobreposição do alerta 3601.
- Capacidade de acessar a funcionalidade de troca da agulha diretamente a partir de uma sobreposição do alerta 3509.
- Melhoria do processo de esvaziamento da solução salina do saco de plasma antes da coleta de plasma usando uma configuração de volume máximo do ciclo muito baixo.
- Melhorias nas verificações do kit para eliminar sobreposições falsas do alerta 2103.
- Limite maior de caracteres para varredura de códigos de Lote e REF de produtos não duráveis (por exemplo, contêineres de solução salina, ACD e PAS).

Anomalias

Entre em contato com seu representante local da Fresenius Kabi para obter uma lista de anomalias associadas a esta versão.

Lista de Materiais de Segurança Cibernética (CBOM)

A CBOM para a versão 2.1 do Sistema de Aférese AmiCORE é descrita pelos seguintes arquivos XML.

A CBOM a seguir é comum às versões 2.1J (2.1.72.673) e 2.1I (2.1.70.670) do software:

```
<?xml version="1.0"?>
<CBOM>
  <Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>6.5.0 SP1</Version>
    <Description>Realtime Operating System used in AmiCORE
    MPU</Description>
    <ThreatVectors>
```

```

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        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 3336</Version>
    <Description>Byte Pair Encoding</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 3792</Version>
    <Description>Applypatch</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4004</Version>
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    <ThreatVectors>
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        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
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    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4703</Version>
    <Description>Kernel and Libc</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>

```

```
</Item>
<Item>
  <Vendor>BlackBerry/QNX</Vendor>
  <Name>Neutrino RTOS</Name>
  <Version>Patch 4772</Version>
  <Description>Procnto - Microkernel and process manager
</Description>
  <ThreatVectors>
    <Vector>LAN</Vector>
    <Vector>Wi-Fi</Vector>
    <Vector>USB</Vector>
    <Vector>UI</Vector>
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</Item>
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  <Name>Neutrino RTOS</Name>
  <Version>Patch 4880</Version>
  <Description>Kernel Libc</Description>
  <ThreatVectors>
    <Vector>LAN</Vector>
    <Vector>Wi-Fi</Vector>
    <Vector>USB</Vector>
    <Vector>UI</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>BlackBerry/QNX</Vendor>
  <Name>Photon microGUI Library</Name>
  <Version>6.5.0</Version>
  <Description>microGUI library for creating UI</Description>
  <ThreatVectors>
    <Vector>UI</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>BlackBerry/QNX</Vendor>
  <Name>USB stack and Library</Name>
  <Version>6.5.0</Version>
  <Description>Implements USB Protocol. Also supplies class
drivers to communicate with USB stack</Description>
  <ThreatVectors>
    <Vector>USB</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>GnuPG Project</Vendor>
  <Name>GnuPG</Name>
  <Version>1.4.11</Version>
  <Description>Security utility used for verifying digital
signatures during software upgrades</Description>
  <ThreatVectors>
    <Vector>USB</Vector>
```

```

        </ThreatVectors>
    </Item>
    <Item>
        <Vendor>Expect Project</Vendor>
        <Name>Expect</Name>
        <Version>5.43.0</Version>
        <Description>Scripting language used for configuring network
        interfaces</Description>
        <ThreatVectors>
            <Vector>LAN</Vector>
            <Vector>Wi-Fi</Vector>
        </ThreatVectors>
    </Item>
    <Item>
        <Vendor>haxx</Vendor>
        <Name>libcurl</Name>
        <Version>7.19.6</Version>
        <Description>client side URL transfer library</Description>
        <ThreatVectors>
            <Vector>LAN</Vector>
            <Vector>Wi-Fi</Vector>
        </ThreatVectors>
    </Item>
</CBOM>

```

A CBOM a seguir é comum às versões 2.1H (2.1.63.604), 2.1G (2.1.61.585), 2.1E (2.1.53.552) e 2.1D (2.1.47.541) do software:

```

<?xml version="1.0"?>
<CBOM>
    <Item>
        <Vendor>BlackBerry/QNX</Vendor>
        <Name>Neutrino RTOS</Name>
        <Version>6.5.0 SP1</Version>
        <Description>Realtime Operating System used in AmiCORE
        MPU</Description>
        <ThreatVectors>
            <Vector>LAN</Vector>
            <Vector>Wi-Fi</Vector>
            <Vector>USB</Vector>
            <Vector>UI</Vector>
        </ThreatVectors>
    </Item>
    <Item>
        <Vendor>BlackBerry/QNX</Vendor>
        <Name>Neutrino RTOS</Name>
        <Version>Patch 3336</Version>
        <Description>Byte Pair Encoding</Description>
        <ThreatVectors>
            <Vector>LAN</Vector>
            <Vector>Wi-Fi</Vector>
        </ThreatVectors>
    </Item>
</CBOM>

```

```

        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 3792</Version>
    <Description>Applypatch</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4004</Version>
    <Description>TCP Timer</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4703</Version>
    <Description>Kernel and Libc</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4772</Version>
    <Description>Procnto - Microkernel and process manager
    </Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>

```

```
<Item>
  <Vendor>BlackBerry/QNX</Vendor>
  <Name>Photon microGUI Library</Name>
  <Version>6.5.0</Version>
  <Description>microGUI library for creating UI</Description>
  <ThreatVectors>
    <Vector>UI</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>BlackBerry/QNX</Vendor>
  <Name>USB stack and Library</Name>
  <Version>6.5.0</Version>
  <Description>Implements USB Protocol. Also supplies class
drivers to communicate with USB stack</Description>
  <ThreatVectors>
    <Vector>USB</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>GnuPG Project</Vendor>
  <Name>GnuPG</Name>
  <Version>1.4.11</Version>
  <Description>Security utility used for verifying digital
signatures during software upgrades</Description>
  <ThreatVectors>
    <Vector>USB</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>Expect Project</Vendor>
  <Name>Expect</Name>
  <Version>5.43.0</Version>
  <Description>Scripting language used for configuring network
interfaces</Description>
  <ThreatVectors>
    <Vector>LAN</Vector>
    <Vector>Wi-Fi</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>haxx</Vendor>
  <Name>libcurl</Name>
  <Version>7.19.6</Version>
  <Description>client side URL transfer library</Description>
  <ThreatVectors>
    <Vector>LAN</Vector>
    <Vector>Wi-Fi</Vector>
  </ThreatVectors>
</Item>
</CBOM>
```

O formato da CBOM é definido pelo seguinte XSD:

```
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elementFormDefault="qualified" xmlns:xs="http://www.w3.org/2001/
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<xs:element name="CBOM">
<xs:complexType>
<xs:sequence>
<xs:element name="Item" maxOccurs="unbounded" minOccurs="1">
<xs:complexType>
<xs:sequence>
<xs:element type="xs:string" name="Vendor"/>
<xs:element type="xs:string" name="Name"/>
<xs:element type="xs:string" name="Version"/>
<xs:element type="xs:string" name="Description"/>
<xs:element name="ThreatVectors">
<xs:complexType>
<xs:sequence>
<xs:element type="xs:string" name="Vector"
maxOccurs="unbounded" minOccurs="1"/>
</xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
</xs:schema>
```

A CBOM a seguir aplica-se à versão 2.1K (2.1.77.701) do software:

```
<?xml version="1.0"?>
<CBOM>
  <Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>6.5.0 SP1</Version>
    <Description>Realtime Operating System used in AmiCORE
    MPU</Description>
    <ThreatVectors>
      <Vector>LAN</Vector>
      <Vector>Wi-Fi</Vector>
      <Vector>USB</Vector>
      <Vector>UI</Vector>
    </ThreatVectors>
  </Item>
  <Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 3336</Version>
```

```

    <Description>Byte Pair Encoding</Description>
    <ThreatVectors>
      <Vector>LAN</Vector>
      <Vector>Wi-Fi</Vector>
      <Vector>USB</Vector>
      <Vector>UI</Vector>
    </ThreatVectors>
  </Item>
  <Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 3792</Version>
    <Description>Applypatch</Description>
    <ThreatVectors>
      <Vector>LAN</Vector>
      <Vector>Wi-Fi</Vector>
      <Vector>USB</Vector>
      <Vector>UI</Vector>
    </ThreatVectors>
  </Item>
  <Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4004</Version>
    <Description>TCP Timer</Description>
    <ThreatVectors>
      <Vector>LAN</Vector>
      <Vector>Wi-Fi</Vector>
      <Vector>USB</Vector>
      <Vector>UI</Vector>
    </ThreatVectors>
  </Item>
  <Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4703</Version>
    <Description>Kernel and Libc</Description>
    <ThreatVectors>
      <Vector>LAN</Vector>
      <Vector>Wi-Fi</Vector>
      <Vector>USB</Vector>
      <Vector>UI</Vector>
    </ThreatVectors>
  </Item>
  <Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4772</Version>
    <Description>Procnto - Microkernel and process manager
    </Description>
    <ThreatVectors>
      <Vector>LAN</Vector>
      <Vector>Wi-Fi</Vector>

```

```

        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4880</Version>
    <Description>Kernel Libc</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
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    <Name>Neutrino RTOS</Name>
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    <Description>Libimg Patch</Description>
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        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Photon microGUI Library</Name>
    <Version>6.5.0</Version>
    <Description>microGUI library for creating UI</Description>
    <ThreatVectors>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>USB stack and Library</Name>
    <Version>6.5.0</Version>
    <Description>Implements USB Protocol. Also supplies class
    drivers to communicate with USB stack</Description>
    <ThreatVectors>
        <Vector>USB</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>GnuPG Project</Vendor>
    <Name>GnuPG</Name>
    <Version>1.4.11</Version>
    <Description>Security utility used for verifying digital
    signatures during software upgrades</Description>

```

```

    <ThreatVectors>
      <Vector>USB</Vector>
    </ThreatVectors>
  </Item>
  <Item>
    <Vendor>Expect Project</Vendor>
    <Name>Expect</Name>
    <Version>5.43.0</Version>
    <Description>Scripting language used for configuring network
    interfaces</Description>
    <ThreatVectors>
      <Vector>LAN</Vector>
      <Vector>Wi-Fi</Vector>
    </ThreatVectors>
  </Item>
  <Item>
    <Vendor>haxx</Vendor>
    <Name>libcurl</Name>
    <Version>7.64.0</Version>
    <Description>client side URL transfer library</Description>
    <ThreatVectors>
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      <Vector>Wi-Fi</Vector>
    </ThreatVectors>
  </Item>
</CBOM>

```

A CBOM a seguir aplica-se à versão 2.1L (2.1.82.735) do software:

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<?xml version="1.0"?>
<CBOM>
  <Item>
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    <Name>Neutrino RTOS</Name>
    <Version>6.5.0 SP1</Version>
    <Description>Realtime Operating System used in AmiCORE
    MPU</Description>
    <ThreatVectors>
      <Vector>LAN</Vector>
      <Vector>Wi-Fi</Vector>
      <Vector>USB</Vector>
      <Vector>UI</Vector>
    </ThreatVectors>
  </Item>
  <Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 3336</Version>
    <Description>Byte Pair Encoding</Description>
    <ThreatVectors>
      <Vector>LAN</Vector>
      <Vector>Wi-Fi</Vector>
    </ThreatVectors>
  </Item>
</CBOM>

```

```

        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 3792</Version>
    <Description>Applypatch</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4004</Version>
    <Description>TCP Timer</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4703</Version>
    <Description>Kernel and Libc</Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>
<Item>
    <Vendor>BlackBerry/QNX</Vendor>
    <Name>Neutrino RTOS</Name>
    <Version>Patch 4772</Version>
    <Description>Procnto - Microkernel and process manager
    </Description>
    <ThreatVectors>
        <Vector>LAN</Vector>
        <Vector>Wi-Fi</Vector>
        <Vector>USB</Vector>
        <Vector>UI</Vector>
    </ThreatVectors>
</Item>

```

```
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  <Vendor>BlackBerry/QNX</Vendor>
  <Name>Neutrino RTOS</Name>
  <Version>Patch 4880</Version>
  <Description>Kernel Libc</Description>
  <ThreatVectors>
    <Vector>LAN</Vector>
    <Vector>Wi-Fi</Vector>
    <Vector>USB</Vector>
    <Vector>UI</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>BlackBerry/QNX</Vendor>
  <Name>Neutrino RTOS</Name>
  <Version>Patch 4924</Version>
  <Description>Libimg Patch</Description>
  <ThreatVectors>
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    <Vector>Wi-Fi</Vector>
    <Vector>USB</Vector>
    <Vector>UI</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>BlackBerry/QNX</Vendor>
  <Name>Photon microGUI Library</Name>
  <Version>6.5.0</Version>
  <Description>microGUI library for creating UI</Description>
  <ThreatVectors>
    <Vector>UI</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>BlackBerry/QNX</Vendor>
  <Name>USB stack and Library</Name>
  <Version>6.5.0</Version>
  <Description>Implements USB Protocol. Also supplies class
  drivers to communicate with USB stack</Description>
  <ThreatVectors>
    <Vector>USB</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>GnuPG Project</Vendor>
  <Name>GnuPG</Name>
  <Version>1.4.11</Version>
  <Description>Security utility used for verifying digital
  signatures during software upgrades</Description>
  <ThreatVectors>
    <Vector>USB</Vector>
  </ThreatVectors>
</Item>
```

```
<Item>
  <Vendor>Expect Project</Vendor>
  <Name>Expect</Name>
  <Version>5.43.0</Version>
  <Description>Scripting language used for configuring network
    interfaces</Description>
  <ThreatVectors>
    <Vector>LAN</Vector>
    <Vector>Wi-Fi</Vector>
  </ThreatVectors>
</Item>
<Item>
  <Vendor>haxx</Vendor>
  <Name>libcurl</Name>
  <Version>7.64.0</Version>
  <Description>client side URL transfer library</Description>
  <ThreatVectors>
    <Vector>LAN</Vector>
    <Vector>Wi-Fi</Vector>
  </ThreatVectors>
</Item>
</CBOM>
```


**Fresenius Kabi AG**

Else-Kröner-Str. 1
61352 Bad Homburg
Germany
Tel.: +49 (0) 61 72 / 686-0
www.fresenius-kabi.com
www.fresenius-kabi.com/us/symbolglossary



Unidade de produção /
Fabricado por:

Plexus Manufacturing Sdn. Bhd.*

Plot 87, Lebuhraya Kampung Jawa
11900 Bayan Lepas
Penang, Malaysia



Unidade de produção /
Fabricado por:

Fresenius HemoCare GmbH*

Gruener Weg 10
61169 Friedberg
Germany



Unidade de produção /
Fabricado por:

Fresenius Vial S.A.S.*

Le Grand Chemin,
38590 Brézins, France

Registrado por:

Fresenius HemoCare Brasil Ltda.

Rua Roque Gonzales, 128
06855-690, Jardim Branca Flor
Itapeverica da Serra – SP Brasil
SAC: 0800 707 3855
C.N.P.J. 49.601107/0001-84

Incorpora produto homologado pela
ANATEL sob número **17465-21-04985**.

Este equipamento não tem direito à
proteção contra interferência prejudicial
e não pode causar interferência em
sistemas devidamente autorizados

Para mais informações, consulte o site
da Anatel
<https://www.gov.br/anatel>

Registro ANVISA nº. 10154450212

Nota: os Kits de Aférese descartáveis
mencionados nestas instruções de uso,
são registrados separadamente.

*Consulte o rótulo do instrumento quanto ao local de fabricação de cada dispositivo.

Projetado nos EUA

Todas as marcas exibidas pertencem aos respectivos proprietários.

