

By Royal Charter

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.****CE 684926**

Issued To:

**Wallaby Medical, Inc  
22901 Mill Creek Drive  
Laguna Hills  
California  
92653  
USA**

In respect of:

**Detachment Coil System**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-08-30**Date: **2021-05-11**Expiry Date: **2024-05-26**

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# EC Design-Examination Certificate

## Supplementary Information to CE 684926

Issued To:

**Wallaby Medical, Inc**  
**22901 Mill Creek Drive**  
**Laguna Hills**  
**California**  
**92653**  
**USA**

Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
18CFR06016	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 6mm x 16cm	<p>The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.</p> <p>The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.</p>	Class III Implant
18CFR07019	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 7mm x 19cm		
18CFR08027	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 8mm x 27cm		
18CFR09030	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 9mm x 30cm		
18CFR10034	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 10mm x 34cm		
18CFR11037	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 11mm x 37cm		
18CFR12040	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 12mm x 40cm		

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
18CFR13043	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 13mm x 43cm	<p>The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.</p> <p>The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.</p>	Class III Implant
18CFR14047	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 14mm x 47cm		
18CFR15050	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 15mm x 50cm		
18CFR16050	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 16mm x 50cm		
18CFR18050	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 18mm x 50cm		
18CFR20050	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 20mm x 50cm		
18CFR22050	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 22mm x 50cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
18CFR25050	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 25mm x 50cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.	Class III Implant
18CFR25060	Wallaby Avenir™ Coil System	18 System Complex Framing Coil 25mm x 60cm		
10CFR02002	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 2mm x 2cm	The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	
10CFR02003	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 2mm x 3cm		
10CFR02006	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 2mm x 6cm		
10CFR02505	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 2.5mm x 5cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10CFR03004	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 3mm x 4cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.	Class III Implant
10CFR03006	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 3mm x 6cm		
10CFR03506	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 3.5mm x 6cm	The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	
10CFR04007	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 4mm x 7cm		
10CFR04013	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 4mm x 13cm		
10CFR05008	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 5mm x 8cm		
10CFR05017	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 5mm x 17cm		
10CFR06011	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 6mm x 11cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10CFR06020	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 6mm x 20cm	<p>The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.</p> <p>The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.</p>	Class III Implant
10CFR07013	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 7mm x 13cm		
10CFR07024	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 7mm x 24cm		
10CFR08016	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 8mm x 16cm		
10CFR08027	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 8mm x 27cm		
10CFR09023	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 9mm x 23cm		
10CFR09030	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 9mm x 30cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10CFR10027	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 10mm x 27cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.  The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	Class III Implant
10CFR10034	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 10mm x 34cm		
10HFL03004	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 3mm x 4cm		
10HFL03006	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 3mm x 6cm		
10HFL03008	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 3mm x 8cm		
10HFL03010	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 3mm x 10cm		
10HFL04004	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 4mm x 4cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10HFL04006	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 4mm x 6cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.  The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	Class III Implant
10HFL04008	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 4mm x 8cm		
10HFL04010	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 4mm x 10cm		
10HFL04015	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 4mm x 15cm		
10HFL04020	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 4mm x 20cm		
10HFL05010	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 5mm x 10cm		
10HFL05015	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 5mm x 15cm		

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10HFL05020	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 5mm x 20cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.  The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	Class III Implant
10HFL06010	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 6mm x 10cm		
10HFL06015	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 6mm x 15cm		
10HFL06020	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 6mm x 20cm		
10HFL07015	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 7mm x 15cm		
10HFL07020	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 7mm x 20cm		
10HFL07030	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 7mm x 30cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10HFL08020	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 8mm x 20cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.	Class III Implant
10HFL08030	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 8mm x 30cm		
10HFL09030	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 9mm x 30cm	The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	
10HFL10030	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 10mm x 30cm		
10CFN01002	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 1mm x 2cm		
10CFN01502	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 1.5mm x 2cm		
10CFN01503	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 1.5mm x 3cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10CFN01504	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 1.5mm x 4cm	<p>The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.</p> <p>The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.</p>	Class III Implant
10CFN02002	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2mm x 2cm		
10CFN02003	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2mm x 3cm		
10CFN02004	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2mm x 4cm		
10CFN02006	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2mm x 6cm		
10CFN02503	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2.5mm x 3cm		
10CFN02504	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2.5mm x 4cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10CFN03004	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 3mm x 4cm	<p>The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.</p> <p>The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.</p>	Class III Implant
10CFN03006	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 3mm x 6cm		
10CFN03008	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 3mm x 8cm		
10CFN03010	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 3mm x 10cm		
10CFN04006	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 4mm x 6cm		
10CFN04008	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 4mm x 8cm		
10CFN04010	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 4mm x 10cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10CFN05008	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 5mm x 8cm	<p>The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.</p> <p>The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.</p>	Class III Implant
10CFN05010	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 5mm x 10cm		
10HFN01002	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 1mm x 2cm		
10HFN01501	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 1.5mm x 1cm		
10HFN01502	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 1.5mm x 2cm		
10HFN01503	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 1.5mm x 3cm		
10HFN01504	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 1.5mm x 4cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10HFN01506	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 1.5mm x 6cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.  The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	Class III Implant
10HFN02001	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 2mm x 1cm		
10HFN02002	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 2mm x 2cm		
10HFN02003	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 2mm x 3cm		
10HFN02004	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 2mm x 4cm		
10HFN02006	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 2mm x 6cm		
10HFN02008	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 2mm x 8cm		

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10HFN02503	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 2.5mm x 3cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.	Class III Implant
10HFN02504	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 2.5mm x 4cm		
10HFN02506	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 2.5mm x 6cm	The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	
10HFN03004	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 3mm x 4cm		
10HFN03006	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 3mm x 6cm		
10HFN03008	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 3mm x 8cm		
10HFN03010	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 3mm x 10cm		

First Issued: **2019-08-30**Date: **2021-05-11**Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 684926

Issued To:

**Wallaby Medical, Inc**  
**22901 Mill Creek Drive**  
**Laguna Hills**  
**California**  
**92653**  
**USA**

Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10HFN03504	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 3.5mm x 4cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.	Class III Implant
10HFN03506	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 3.5mm x 6cm		
10HFN03508	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 3.5mm x 8cm	The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	
10HFN04006	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 4mm x 6cm		
10HFN04008	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 4mm x 8cm		
10HFN04010	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 4mm x 10cm		
10HFN05006	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 5mm x 6cm		

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**USA**

Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10HFN05008	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 5mm x 8cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.  The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and venous embolization in the peripheral vasculature.	Class III Implant
10HFN05010	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 5mm x 10cm		
10HFN06006	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 6mm x 6cm		
10HFN06008	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 6mm x 8cm		
10HFN06010	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 6mm x 10cm		

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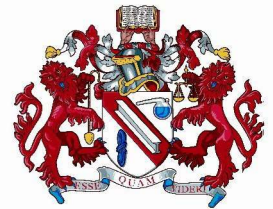
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# EC Design-Examination Certificate

## Supplementary Information to CE 684926

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**Wallaby Medical, Inc**  
**22901 Mill Creek Drive**  
**Laguna Hills**  
**California**  
**92653**  
**USA**

## Certificate History

Date	Reference Number	Action
30 August 2019	8858411	Initial Issue.
Current	3385412	Change of "Issued to" address to 22901 Mill Creek Drive, Laguna Hills California, 92653, USA.

First Issued: **2019-08-30**Date: **2021-05-11**Expiry Date: **2024-05-26**

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