INFORMAÇÕES DE REGISTRO	
Título do Registro: CE035 - Technical File - Solaris	
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Aprovado por: Eduardo Cordeiro Luciano Curado	**Data de aprovação:** 31/10/2022

Technical File

Applied Standards:	EN ISO 13485: 2016, MDD 93/42 EC as amended by 2007/47 EC
Generic Name of the device:	Vascular Stent Graft
Brand Name:	SOLARIS
Trade Name: **GMDN code:**	Solaris Vascular Stent Graft 43526 Iliofemoral artery endovascular stent-graft
Manufacturer:	SCITECH PRODUTOS MÉDICOS SA.
Address:	Rua 18, S/N, Quadra Área, Lote 0006, Galpão 01, Bairro: Polo Empresarial Goiás – Etapa 1A, Aparecida de Goiânia, Goiás, Brasil, CEP 74985-249. T: + 55 (62) 3625 5018 / F: +55 (62) 4008-0800 www.scitechmed.com

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1. Product Description

1.1. Basic Information

1.1.1. Manufacturer / EU Representative

Manufacturer: **Scitech Produtos Médicos SA.** Address: Rua 18, S/N, Quadra Área, Lote, 0006, Galpão 01, Bairro: Polo Empresarial Goiás – Etapa 1A Aparecida de Goiânia, Goiás, Brasil, CEP 74985-249.
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1.1.2. General description of the device

Solaris Vascular Stent Graft consists of a stent and its delivery system. The stent is self-expandable made of a super elastic metal alloy (nitinol) encapsulated with PTFE membrane along the entire length, except at the ends of the stent prosthesis where radiopaque, tantalum markers are located to delineate the ends of the stent. The delivery system is Pull Back and OTW (Over the Wire) type that consists of concentric tubes. The compatible guidewire is 0.035”and to release the stent the proximal part of the catheter must be held still and the Y connector must be pulled towards the operator (Pull Back).

Table 1. Product Components

	Solaris Vascular Stent Graft
IMPLANT	Stent
	PTFE
DELIVERY SYSTEM	Y Connector
	female Connector 1
	Extern tube
	Metallic tube
	Intern tube
	Intermediate tube
	Anti-Jump
	Marker band
	Female Connector 2
	No toxic PVC tube
	Soft tip
	Handle

1.1.2.1. Models

Table 2. Models and References – 9Fr

Code	Description
128090	SOLARIS VASCULAR STENT GRAFT 06X040MM 130CM SCI
128091	SOLARIS VASCULAR STENT GRAFT 06X060MM 130CM SCI
128092	SOLARIS VASCULAR STENT GRAFT 06X080MM 130CM SCI
128438	SOLARIS VASCULAR STENT GRAFT 06X100MM 130CM SCI
128093	SOLARIS VASCULAR STENT GRAFT 07X040MM 130CM SCI
128094	SOLARIS VASCULAR STENT GRAFT 07X060MM 130CM SCI
128095	SOLARIS VASCULAR STENT GRAFT 07X080MM 130CM SCI
128439	SOLARIS VASCULAR STENT GRAFT 07X100MM 130CM SCI
128096	SOLARIS VASCULAR STENT GRAFT 08X040MM 130CM SCI
128097	SOLARIS VASCULAR STENT GRAFT 08X060MM 130CM SCI
128098	SOLARIS VASCULAR STENT GRAFT 08X080MM 130CM SCI
128440	SOLARIS VASCULAR STENT GRAFT 08X100MM 130CM SCI
128099	SOLARIS VASCULAR STENT GRAFT 09X040MM 130CM SCI
128100	SOLARIS VASCULAR STENT GRAFT 09X060MM 130CM SCI
128101	SOLARIS VASCULAR STENT GRAFT 09X080MM 130CM SCI
128441	SOLARIS VASCULAR STENT GRAFT 09X100MM 130CM SCI

Table 3. Models and References – 8Fr

Code	Description
128442	SOLARIS VASCULAR STENT GRAFT 05X40MM 8FR 130CM SCI

128443	SOLARIS VASCULAR STENT GRAFT 05X60MM 8FR 130CM SCI
128444	SOLARIS VASCULAR STENT GRAFT 05X80MM 8FR 130CM SCI
128445	SOLARIS VASCULAR STENT GRAFT 05X100MM 8FR 130CM SC
128446	SOLARIS VASCULAR STENT GRAFT 06X40MM 8FR 130CM SCI
128447	SOLARIS VASCULAR STENT GRAFT 06X60MM 8FR 130CM SCI
128448	SOLARIS VASCULAR STENT GRAFT 06X80MM 8FR 130CM SCI
128449	SOLARIS VASCULAR STENT GRAFT 07X40MM 8FR 130CM SCI
128450	SOLARIS VASCULAR STENT GRAFT 07X60MM 8FR 130CM SCI
128451	SOLARIS VASCULAR STENT GRAFT 07X80MM 8FR 130CM SCI
128943	SOLARIS VASCULAR STENT GRAFT 08X40MM 8FR 130CM SCI
128944	SOLARIS VASCULAR STENT GRAFT 08X60MM 8FR 130CM SCI
128945	SOLARIS VASCULAR STENT GRAFT 08X80MM 8FR 130CM SCI

1.1.3. Indications for use

• In the treatment of in-stent restenosis in the venous outflow of hemodialysis patients dialyzing by either an arteriovenous (AV) fistula or AV graft.

• In the treatment of stenosis in the venous outflow of hemodialysis patients dialyzing by an AV graft.

• Restenosis or reocclusion (except vessels on the Central Circulatory System* and Central Nervous System**)

• Dissection (except vessels on the Central Circulatory System and Central Nervous System)

• Residual stenosis with impaired perfusion (pressure gradient) following balloon dilatation, especially in stages III and IV according to Fontaine; (except vessels on the Central Circulatory System and Central Nervous System)

• Detached arteriosclerotic plaque material and luminal obstruction following balloon dilatation. (except vessels on the Central Circulatory System and Central Nervous System)

• Occlusion after thrombolysis or after aspiration and before dilatation. (except vessels on the Central Circulatory System and Central Nervous System).

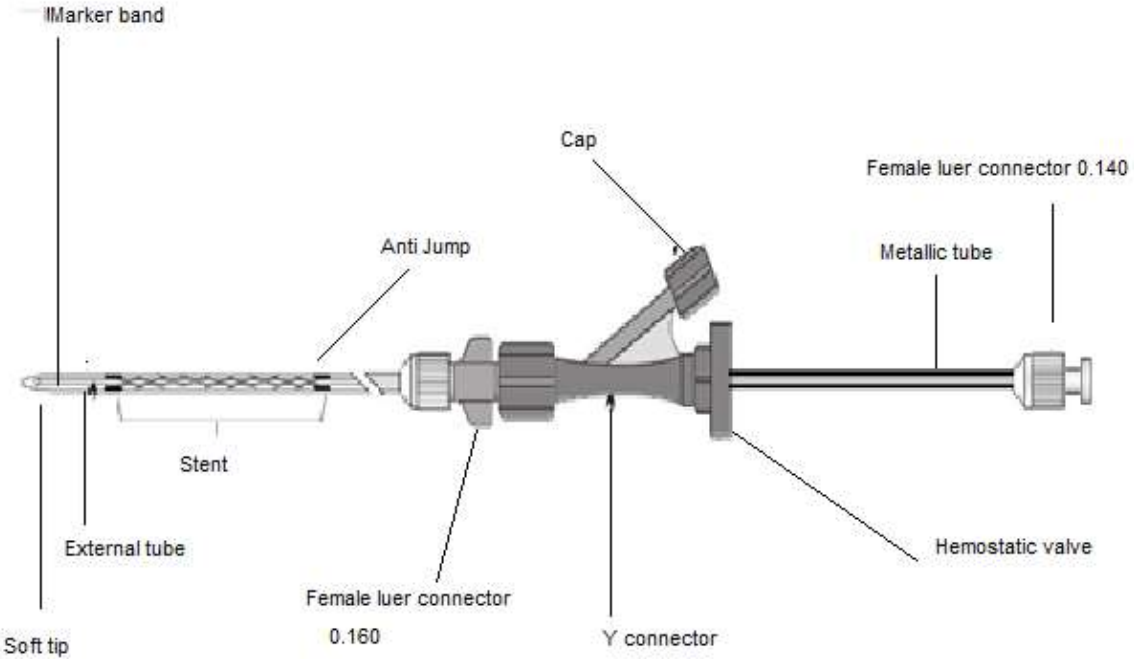
Central Circulatroy System - pulmonary arteries, ascending aorta, aortic arch, descending aorta to aortic bifurcation, coronary arteries, common carotid artery, external carotid artery, internal carotid artery, cerebral arteries, brachycephalic trunk, coronary veins, pulmonary veins, superior vena cava and vena cava Inferior

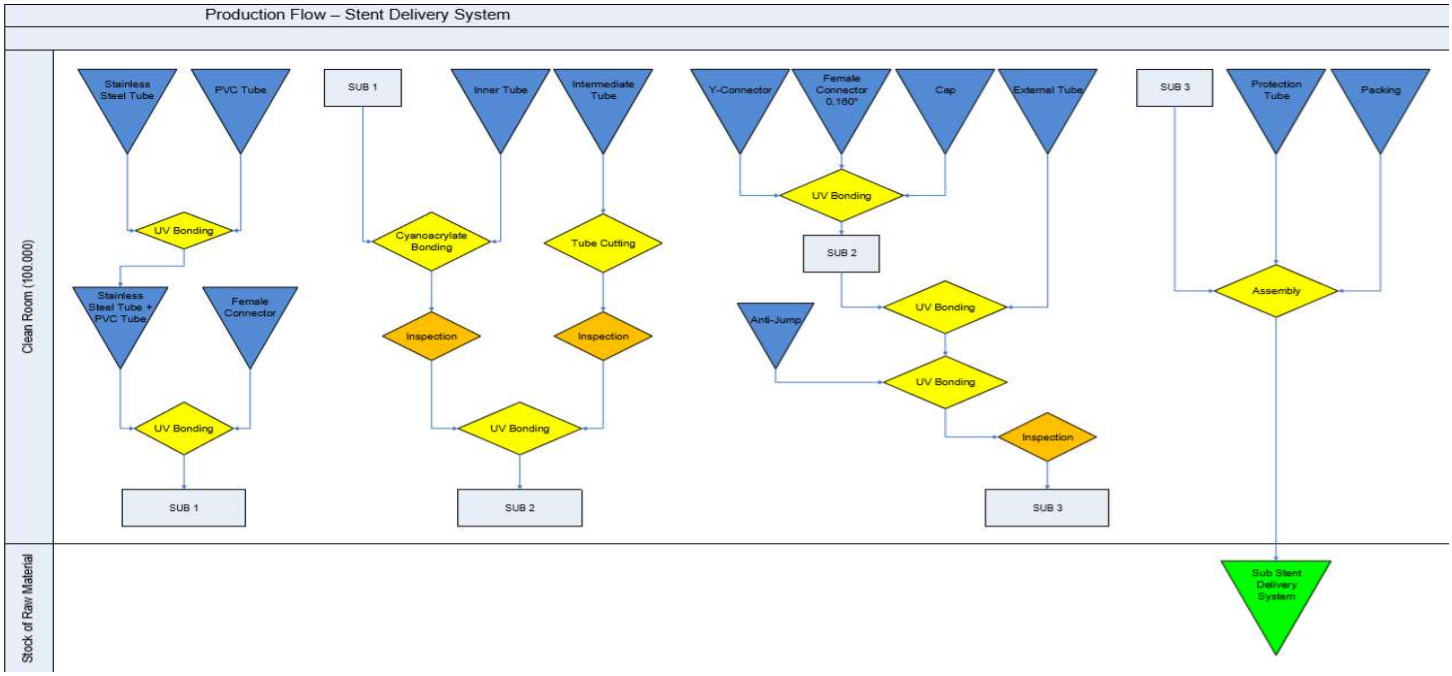
Central Nervous System - the brain, the meninges, and the spinal cord.

1.2. Classification

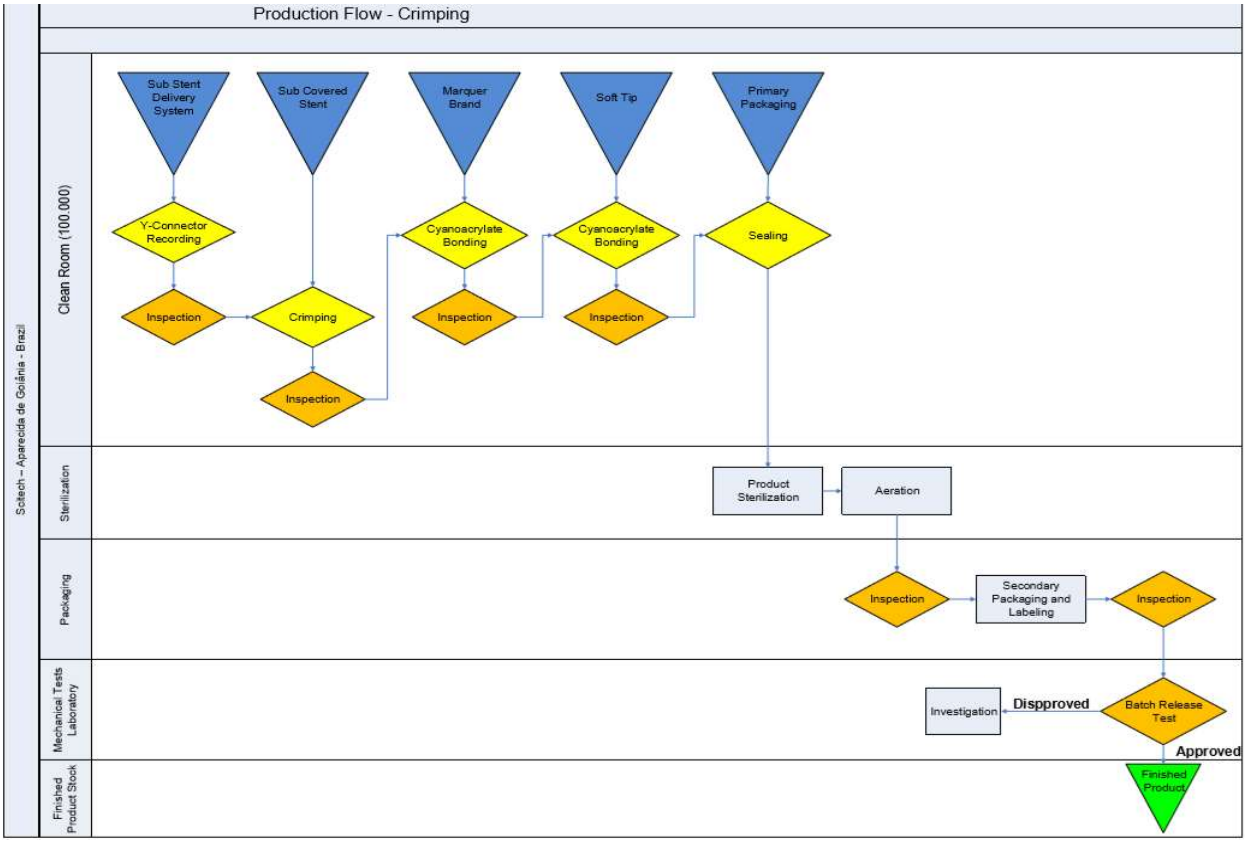
Solaris Vascular Stent Graft is a Class IIb medical device. This classification is determined by application of Rule 8, Section 2.4, Chapter III of Annex IX. As per the MEDDEV 2.4/1 Rev.9 June 2010, Pheripheral Vascular Grafts and stents are classified as class IIb.

1.3. Drawings &photographs





1.4. Manufacturing Flowchart



1.5. Quality Standards

Scitech Produtos Médicos SA quality system complies with the standard EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes.

All Standards and Guidelines applicable to the Solaris Vascular Stent Graft published in the Official Journal of the European Communities) are addressed in Attachment 1 of Design Dossier part B.

2. History of the device

The Solaris Vascular Stent Graft was registered at Anvisa (National Sanitary Surveillance Agency) by the registration number 10413960173 and it has been commercially available in Brazil since April/2017.

Detailed information regarding the sales history of the device is available on PMS documents.

3. Design Dossier part B summary information

Design Dossier part B contains detailed information of essential data that demonstrates safety and efficacy of Solaris Vascular Stent Graft.

3.1 Essential requirements (ER) checklist

The Essential Requirements per Council directive 93/42/EEC Annex I. as amended by Directive 2007/47/EC, for a Class IIb medical device, under Annex II is documented in the Essential Requirements Checklist that is provided in **Attachment 1** of Design Dossier part B.

3.2 Risk analysis

Solaris Vascular Stent Graft is designed, developed and tested in accordance with the Scitech Design and Development procedure in which the impact of modifications on device safety and performance is assessed in accordance with the EN ISO 14971:2019, CEN ISO/TR 24971:2020, ISO/TR 14283:2018 and with Scitech internal quality system procedure for risk management. Possible hazards and associated risk related to the device modification andclinical usage of the device were identified, examined and found to be acceptable after the implementation of the mitigation measures such as labeling warnings and instructions for use. The Risk Management Plan and Risk Management Report of Solaris Vascular Stent Graft are provided in **Attachment 2** of Design Dossier part B.

3.3 Drawings, design and product specifications

Detailed information of drawings, design and specification of the product is provided in **Attachment 3** of Design Dossier part B.

3.4 Chemical, physical (mechanical safety and performance) and biological tests

Design verification & validation activities were undertaken to confirm that device specifications are adequate to ensure the product is capable of resisting the chemical and

biological environment to which the device will be exposed. Biological tests also ensure that the device is not likely to cause biological reactions in the patient or user. Physical tests are performed to ensure the device is capable of performing in conformance to engineering specifications.

This is the most important part of the design dossier that includes all the reports of In-vitro testing as per EN ISO 25539-1:2017 to get compliance with Essential Requirements mentioned in MDD 93/42/EEC as amended by 2007/47/EC. The details and reports related to In-vivo testing pre-clinical studies, biological evaluation, bio-stability tests, microbiological safety tests are provided in **Attachment 4.**

3.4.1 Device Containing Biological Material

Solaris Vascular Stent Graft does not contain animal or human tissue or their derivatives. The devices are manufactured under controlled conditions as documented the company's quality systemand procedures. The product is manufactured, packaged and sterilized using validated processes that ensure the cleanliness and sterility of the Devices. Microbiological Safety declarations regarding use of animal origin tissue and human blood derivatives/ human tissue in the device are provided in **Attachment 4**.

3.5 Clinical data

The Solaris Vascular Stent Graft design dossier included a clinical evaluation based on a literature review and clinical experiences. Additionally, the plan and report for post market follow up and post marketing surveillance are provided in **Attachment 5.**

3.6 Labels and instructions for use, patient information, advertising material

The label and Instructions for Use (IFU) complies with the requirements of Medical Device Directive 93/42/EEC as amended 2007/47/EC and applicable harmonized standards EN ISO 15223-1: 2021 and EN ISO 20417:2021. Refer to **Attachment 6.**

3.7 Manufacturing

Manufacturing includes the manufacturing site address, the details on critical suppliers along with relevant certificates. The brief manufacturing process with each summarized manufacturing steps are described with flow chart that includes inspection and preventive monitoring steps. Specific environment condition clean room condition (as per EN ISO 14644-7:2004 standard) for manufacturing is also described in this section. Summary of manufacturing methods, quality procedures and certificates are provided in **Attachment 7**.

3.8 Packaging and shelf life

From the experimental results as documented in report, no physical changes are observed in properties of Tyvek used to pack the product under study. All results of Solaris Vascular Stent Graft are in compliance of established specifications of the finished product in accelerated time stability study. So, based on conducted Stability Study it is concluded that Solaris Vascular Stent Graft is stable for 24 months. Packaging information and stability studies report are provided in **Attachment 8.**

3.9 Sterilization

Sterilization process is one of the most critical manufacturing processes and sterilization process validation has been performed in compliance with EN ISO 11135:2014/A1:2019. The section includes sterilization process validation description along with validation report. Product is sterilized by Ethylene Oxide. Detailed information is provided in **Attachment 9.**

3.10 Combination with other medical devices

Solaris Vascular Stent Graft falls within the scope of the Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC. As per this directive, the product is non-active medical device. Product is supplied with single unit of stent self-expanding and the delivery system. It is not supplied in combination with any other Medical Device such as active medical device [90/385/EEC Directive]. No electrical safety measures are tested and required for Solaris Vascular Stent Graft. Once the product interaction with active medical devices and electrical safety aspects are not evaluated, it is not recommended its use in conjunction with this

category of products. Refer to **Attachment 10**.

3.11 Other applicable directives and regulations

Solaris Vascular Stent Graft falls within the scope of the Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC. Product is not combined with any other Medical Device such as active medical device [90/385/EEC Directive] and Personal Protective Equipment [89/686/EEC Directive] are not applicable. The product manufacturing process does not consist of any dangerous preparations. No other directives or regulations are applicable to the product Solaris Vascular Stent Graft. Refer to **Attachment 11**.

3.12 Conclusion

The Product has been evaluated for Conformity Assessment Procedure according to the following Annex of the Directive 93/42/EEC as amended by 2007/47/EC, Annex II excluding Section 4. As per evaluation, it is reasonable to conclude that the benefit of the Solaris Vascular Stent System outweighs the associated risk which is further minimized to acceptable levels. Hence it is confirmed that the product is in conformance and meets requirements of Annex **I** as applicable and is safe to use. Refer to **Attachment 12**.

3.13 Declaration of conformity

Refer to **Attachment 13.**