

REGISTRO

IDENTIFICAÇÃO

FASE

EC Declaration of Conformity

AR001 - V.6

VIGENTE

INFORMAÇÕES DE REGISTRO

Título do Registro: AR001 - EC Declaration of Conformity - Solaris

Versão do Registro: 7

Fase do Registro: Consulta

Aprovado por: Luciano Curado

Data de aprovação: 11/01/2023

EC DECLARATION OF CONFORMITY

Manufacturer:	Scitech Produtos Médicos SA.																																								
Manufacturer's Address:	Rua 18, Quadra área lote 0006, Compl. Galpão 01, Polo Empresarial Goiás – Etapa 1A, CEP 74985-249 Aparecida de Goiânia - GO – Brazil T: +55 (62) 3625-5018/ F: +55 (62) 4008-0800																																								
EU Authorized Representative:	OBELIS S.A. Bd. Général Wahis, 53, 1030 Brussels, Belgium T: +3227325954 F: +3227326003 E: mail@obelis.net																																								
Product Name:	Solaris Vascular Stent Graft 9Fr <table border="1"> <thead> <tr> <th>Code</th><th>Description</th></tr> </thead> <tbody> <tr><td>128090</td><td>SOLARIS VASCULAR STENT GRAFT 06X040MM 130CM SCI</td></tr> <tr><td>128091</td><td>SOLARIS VASCULAR STENT GRAFT 06X060MM 130CM SCI</td></tr> <tr><td>128092</td><td>SOLARIS VASCULAR STENT GRAFT 06X080MM 130CM SCI</td></tr> <tr><td>128438</td><td>SOLARIS VASCULAR STENT GRAFT 06X100MM 130CM SCI</td></tr> <tr><td>128093</td><td>SOLARIS VASCULAR STENT GRAFT 07X040MM 130CM SCI</td></tr> <tr><td>128094</td><td>SOLARIS VASCULAR STENT GRAFT 07X060MM 130CM SCI</td></tr> <tr><td>128095</td><td>SOLARIS VASCULAR STENT GRAFT 07X080MM 130CM SCI</td></tr> <tr><td>128439</td><td>SOLARIS VASCULAR STENT GRAFT 07X100MM 130CM SCI</td></tr> <tr><td>128096</td><td>SOLARIS VASCULAR STENT GRAFT 08X040MM 130CM SCI</td></tr> <tr><td>128097</td><td>SOLARIS VASCULAR STENT GRAFT 08X060MM 130CM SCI</td></tr> <tr><td>128098</td><td>SOLARIS VASCULAR STENT GRAFT 08X080MM 130CM SCI</td></tr> <tr><td>128440</td><td>SOLARIS VASCULAR STENT GRAFT 08X100MM 130CM SCI</td></tr> <tr><td>128099</td><td>SOLARIS VASCULAR STENT GRAFT 09X040MM 130CM SCI</td></tr> <tr><td>128100</td><td>SOLARIS VASCULAR STENT GRAFT 09X060MM 130CM SCI</td></tr> <tr><td>128101</td><td>SOLARIS VASCULAR STENT GRAFT 09X080MM 130CM SCI</td></tr> <tr><td>128441</td><td>SOLARIS VASCULAR STENT GRAFT 09X100MM 130CM SCI</td></tr> </tbody> </table> 8Fr <table border="1"> <thead> <tr> <th>Code</th><th>Description</th></tr> </thead> <tbody> <tr><td>128442</td><td>SOLARIS VASCULAR STENT GRAFT 05X40MM 8FR 130CM SCI</td></tr> <tr><td>128443</td><td>SOLARIS VASCULAR STENT GRAFT 05X60MM 8FR 130CM SCI</td></tr> </tbody> </table>	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	Code	Description	128442	SOLARIS VASCULAR STENT GRAFT 05X40MM 8FR 130CM SCI	128443	SOLARIS VASCULAR STENT GRAFT 05X60MM 8FR 130CM SCI
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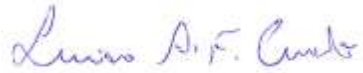
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Basic UDI:	Not Applicable																						
GMDN Code:	43526 Iliofemoral artery endovascular stent-graft																						
Product Classification:	Class IIb as per the applicable classification rules for Peripheral Vascular Grafts and Stents in Annex IX, Chapter III, Section 2.4 (rule 8) of the MDD 93/42/EEC amended by 2007/47/EC for medical devices.																						
Intended Use:	Solaris Vascular Stent Graft intended use is improving blood flow in patients with symptomatic peripheral arterial disease or treatment of stenosis on arteriovenous fistulas of peripheral vessels.																						
Indications for Use:	The Solaris Vascular Stent Graft is intended to treat the following conditions: • 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 Circulatory 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 inferior vena cava **Central Nervous System** - the brain, the meninges, and the spinal cord																						

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Product Conformity Route:	We herewith declare that the above-mentioned product meets the provisions of the council directive 93/42/EEC amended by 2007/47/EC for medical devices. The obligations laid down in Annex II (excluding the section 4) are fulfilled with a quality system approved for manufacture and final inspection of the products. All supporting documentation is retained at the premises of the manufacturer.
Standards Applied:	EN ISO 13485:2016; EN ISO 14971:2019; CEN ISO/TR 24971:2020; EN ISO 15223-1:2021; EN ISO 20417:2021; EN ISO 10993-1:2020; EN ISO 10993-2:2006; EN ISO 10993-3:2014; EN ISO 10993-4:2017; EN ISO 10993-5:2009; EN ISO 10993-6:2016; EN ISO 10993-7:2008/A1:2022; EN ISO 10993-10:2013; EN ISO 10993-11:2018; EN ISO 10993-12:2021; EN ISO 11607-1:2020; EN ISO 11607-2:2020; EN ISO 11737-1:2018/A1:2021; EN ISO 11737-2:2020; EN ISO 25539-1:2017; EN ISO 7198:2017; EN ISO 80369-7:2021; EN ISO 14644-1:2015; EN ISO 14644-2:2015; EN ISO 14644-7:2004; EN ISO 11135:2014/A1:2019; EN ISO 14155:2020; ISO/TR 14283:2018; ISO 2859-1:1999/A1:2011; ISO 14698-1:2003.
Notified Body:	3EC International a.s. NB2265 Hraničná 18 Bratislava 82105 Country: Slovakia e-mail: katarina.srdosova@3ec.sk
EC Certificate:	Certificate n° 2019-MDD/QS-055/B
Signature:	
Name and Position:	<u>Luciano Curado – CTO</u>
Place/ Date:	Aparecida de Goiânia, Goiás, Brazil Date: May 24, 2021