INFORMAÇÕES DE REGISTRO	
Título do Registro: AR001 - EC Declaration of Conformity - Inspiron	
Versão do Registro: 5	**Fase do Registro:** Consulta
Aprovado por: Luciano Curado	**Data de aprovação:** 13/04/2021

EC DECLARATION OF CONFORMITY

Manufacturer:	Scitech Produtos Médicos SA
Manufacturer's 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
EU Authorized Representative:	OBELIS S.A. Bd Général Wahis, 53, 1030 Brussels, Belgium T: +3227325954 F: +3227326003 E-mail: mail@obelis.net
Product Name:	Inspiron Sirolimus Eluting Stent

105181	STENT INSPIRON 2.25 X 13 MM
105184	STENT INSPIRON 2.25 X 16 MM
105186	STENT INSPIRON 2.25 X 19 MM
105187	STENT INSPIRON 2.25 X 23 MM
105188	STENT INSPIRON 2.25 X 29 MM
105025	STENT INSPIRON 2.50 X 13 MM
102633	STENT INSPIRON 2.50 X 16 MM
102632	STENT INSPIRON 2.50 X 19 MM
105028	STENT INSPIRON 2.50 X 23 MM
105029	STENT INSPIRON 2.50 X 29 MM
105030	STENT INSPIRON 2.50 X 33 MM
104262	STENT INSPIRON 2.50 X 38 MM
113626	STENT INSPIRON 2.50 X 48 MM
113630	STENT INSPIRON 2.50 X 58 MM
105190	STENT INSPIRON 2.75 X 13 MM
105191	STENT INSPIRON 2.75 X 16 MM
105192	STENT INSPIRON 2.75 X 19 MM
105193	STENT INSPIRON 2.75 X 23 MM
105194	STENT INSPIRON 2.75 X 29 MM
105195	STENT INSPIRON 2.75 X 33 MM
105196	STENT INSPIRON 2.75 X 38 MM

	113627 STENT INSPIRON 2.75 X 48 MM 113631 STENT INSPIRON 2.75 X 58 MM 105032 STENT INSPIRON 3.00 X 13 MM 102634 STENT INSPIRON 3.00 X 16 MM 101335 STENT INSPIRON 3.00 X 19 MM 105034 STENT INSPIRON 3.00 X 23 MM 105037 STENT INSPIRON 3.00 X 29 MM 105038 STENT INSPIRON 3.00 X 33 MM 105041 STENT INSPIRON 3.00 X 38 MM 113628 STENT INSPIRON 3.00 X 48 MM 113632 STENT INSPIRON 3.00 X 58 MM 105044 STENT INSPIRON 3.50 X 13 MM 102635 STENT INSPIRON 3.50 X 16 MM 102636 STENT INSPIRON 3.50 X 19 MM 105047 STENT INSPIRON 3.50 X 23 MM 105048 STENT INSPIRON 3.50 X 29 MM 105051 STENT INSPIRON 3.50 X 33 MM 105052 STENT INSPIRON 3.50 X 38 MM 113629 STENT INSPIRON 3.50 X 48 MM 113633 STENT INSPIRON 3.50 X 58 MM 105198 STENT INSPIRON 4.00 X 13 MM 105199 STENT INSPIRON 4.00 X 16 MM 110964 STENT INSPIRON 4.00 X 19 MM 110965 STENT INSPIRON 4.00 X 23 MM 110966 STENT INSPIRON 4.00 X 29 MM
Product Classification:	Class III as per the applicable classification rules for Drug Eluting Stent, Annex IX, Chapter III, Section 4 (rule 13) of the MDD 93/42/EEC.
Indications/ Intended Purpose:	The Inspiron Sirolimus Eluting Stent is indicated to improve the lumen diameter in patients eligible for Percutaneous Transluminal Angioplasty and Stents procedures with symptomatic ischemia heart disease due to restenotic and internal lesions in native coronary artery with reference vessel diameters of 2.25 mm to 4.00mm.
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 (including the section 4) of the MDD 93/42/EEC

	amended by 2007/47/ EC are fulfilled with a quality system approved for the design, manufacture and final inspection of the products. All supporting documentation is retained at the premises of the manufacturer.
Standards Applied:	MDD 93/42/EEC as amended by 2007/47/EC; EN ISO 13485:2016; EN 1041:2008; EN ISO 15223-1:2016; EN ISO 11737-2:2009; EN ISO 11607-1:2009; EN ISO 11607-2:2006; EN ISO 10993-3:2014; EN ISO 10993-5:2009; EN ISO 10993-7:2008/AC:2009; EN ISO 10993-12:2012; EN ISO 10993-13:2010;ISO 14155:2020; ISO 14971:2019, ISO/TR 24971:2020; ISO 10993-1:2018; ISO 10993-4:2017; ISO 10993-6:2016; ISO 10993-10:2010; ISO 10993-11:2017; ISO 14644-1:2015; ISO 14644-2:2015; ISO/TR 14283:2018; ISO 11737-1:2018; ISO 14644-3:2019; ISO 14644-7:2004; ISO 11135:0214/A1:2018; ISO 10555-4:2013; ISO 5832-5:2005; ISO 16428:2005; ISO 1924-2:2008; ISO 25539-2:2020; EN 14299:2004; IEC 62366-1:2015; ISO 12417-1:2015; ASTM E 499-95; ASTM F1929-15; ASTM F1980-16; ASTM F88/F88M - 15; ASTM F895-84:1984; ASTM D5035-06:2008; ASTM D882-02; ASTM F90; ASTM 2081:06.
Notified Body:	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A., Ul. Pulawska 469, 02-844, Warszawa Country: Poland CE 1434
EC Certificate:	1434-MDD-287/2020 (EC Design Examination); 1434-MDD-288/2020 (Full Quality Assurance System)
First CE- marking	Date: August 2020 Lot Number:048353
Signature: **Name and Position:** **Place/ Date:**	[redacted] Luciano Curado – CTO Aparecida de Goiânia, Goiás, Brazil Date: 13/04/2021