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3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2019-MDD/QS-055/B

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the medical device of Class IIb,

Stents, Stent Delivery Systems
Solaris Vascular Stent Graft
(for detailed list refer to Annex pages 1 and 2)

manufactured by company

Scitech Produtos Médicos SA
Rua 18, Quadra área lote 0006, Compl. Galpão 01, Polo Empresarial Goiás - Etapa 1A,
CEP 74985-249 Aparecida de Goiânia - GO – Brazil

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT_67 and the Final protocol No. 310361B/2021.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if such is required. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.14 15:54:05 EEST
Reason: MoldSign Signature
Location: Moldova

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

At Bratislava, on May 24th, 2021
Version B) supersedes the EC Certificate No. 2019-MDD/QS-055/A issued on September 8th, 2020

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Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
0	Sep 16, 2019	310361	CA Cert, Audit Report No. 310361
A	Sep 8, 2020	310361/A	Change of the company status from LTDA to SA and change of address due to new area subdivisions. The physical company residence did not change.
B	May 24, 2021	310361/B	Added new stent dimensions