

EC Design-Examination Certificate

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

No. **CE 709778**
Issued To: **Stryker Neurovascular**
47900 Bayside Parkway
Fremont
California
94538
USA

In respect of:

Trenza™ Embolization Device

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: **2019-11-06**

Date: **2019-11-06**

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.

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Supplementary Information to CE 709778

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Product Listing

Trenza™ Embolization Device

Model Number	Device Name	Dimensions	Intended Purpose per IFU	Classification
IST00E0611	Trenza™ Embolization Device	6 mm x 11 cm	The Trenza Embolization Device is intended to endovascularly obstruct or occlude blood flow in intracranial aneurysms.	Class III
IST00E0713		7 mm x 13 cm		Class III
IST00E0815		8 mm x 15 cm		Class III
IST00E0916		9 mm x 16 cm		Class III
IST00E1018		10 mm x 18 cm		Class III
IST00E1119		11 mm x 19 cm		Class III
IST00E1221		12 mm x 21 cm		Class III

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Certificate History

Date	Reference Number	Action
Current	9754481	First Issue.

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