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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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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