

DECLARATION OF CONFORMITY

Legal Manufacturer: Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515
USA

Manufacturing Site: Boston Scientific Cork Ltd.
Business and Technology Park
Model Farm Road
Cork, Ireland

European Representative: RAQA Manager
Stryker France S.A.S.
ZAC - Avenue de Satolas Green
69330 Pusignan
France

Product: Guglielmi Detachable Coils (GDC™)
Design Dossier 90652815

Product Category: Prosthesis, Internal Embolization, Neurovascular

Classification: Class III, Rule 8 according to Annex IX of the MDD

We declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

Notified Body: DEKRA Certification B.V.
Utrechtseweg 310
6812 AR Arnhem
P.O. Box 5185
6802 ED Arnhem
The Netherlands
Identification number 0344

Quality Certificate: EN ISO 13485 Certificate # 3805987.002

EC Certificate: Annex II.3 Certificate # 3805987CE01

DE Certificate: Annex II.4 Certificate # 3805987DE03

Signature, Date of Issue:

Signature: Katherine Mack **Date:** 16 SEPT 2011
Katherine Mack
Director of Quality
Stryker Neurovascular

Signature: Ronald C. Allen **Date:** 07 Sept 2011
Ronald C. Allen, Ph.D.
Vice President of Regulatory Affairs
Stryker Neurovascular

GDC™-10 Standard Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M00334010340	GDC-10 Standard 10mm x 30cm	TBD
M00334020440	GDC-10 Standard 2mm x 4cm	TBD
M00334020840	GDC-10 Standard 2mm x 8cm	TBD
M00334030440	GDC-10 Standard 3mm x 4cm	TBD
M00334030640	GDC-10 Standard 3mm x 6cm	TBD
M00334030840	GDC-10 Standard 3mm x 8cm	TBD
M00334031240	GDC-10 Standard 3mm x 12cm	TBD
M00334040640	GDC-10 Standard 4mm x 6cm	TBD
M00334041040	GDC-10 Standard 4mm x 10cm	TBD
M00334051040	GDC-10 Standard 5mm x 10cm	TBD
M00334051540	GDC-10 Standard 5mm x 15cm	TBD
M00334061040	GDC-10 Standard 6mm x 10cm	TBD
M00334062040	GDC-10 Standard 6mm x 20cm	TBD
M00334071040	GDC-10 Standard 7mm x 10cm	TBD
M00334073040	GDC-10 Standard 7mm x 30cm	TBD
M00334081040	GDC-10 Standard 8mm x 10cm	TBD
M00334082040	GDC-10 Standard 8mm x 20cm	TBD
M00334083040	GDC-10 Standard 8mm x 30cm	TBD
M00334091540	GDC-10 Standard 9 mm x 15 cm	TBD
M00334093040	GDC-10 Standard 9mm x 30cm	TBD

GDC™-10 Soft Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M00334120240	GDC-10 Soft 2mm x 2cm	TBD
M00334120340	GDC-10 Soft 2mm x 3cm	TBD
M00334120440	GDC-10 Soft 2mm x 4cm	TBD
M00334120640	GDC-10 Soft 2mm x 6cm	TBD
M00334120840	GDC-10 Soft 2mm x 8cm	TBD
M00334130340	GDC-10 Soft 3mm x 3cm	TBD
M00334130440	GDC-10 Soft 3mm x 4cm	TBD
M00334130640	GDC-10 Soft 3mm x 6cm	TBD
M00334130840	GDC-10 Soft 3mm x 8cm	TBD
M00334131040	GDC-10 Soft 3mm x 10cm	TBD
M00334140440	GDC-10 Soft 4mm x 4cm	TBD
M00334140640	GDC-10 Soft 4mm x 6cm	TBD
M00334140840	GDC-10 Soft 4mm x 8cm	TBD
M00334141040	GDC-10 Soft 4mm x 10cm	TBD

GDC™-10 Soft SR Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M003341201SR40	GDC-10 Soft SR 2mm x 1cm	TBD
M003341202SR40	GDC-10 Soft SR 2mm x 2cm	TBD
M003341203SR40	GDC-10 Soft SR 2mm x 3cm	TBD
M003341204SR40	GDC-10 Soft SR 2mm x 4cm	TBD
M003341206SR40	GDC-10 Soft SR 2mm x 6cm	TBD
M003341208SR40	GDC-10 Soft SR 2mm x 8cm	TBD

GDC™-10 2D Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M00334210340	GDC-10 2D 10mm x 30cm	TBD
M00334230840	GDC-10 2D 3mm x 8cm	TBD
M00334241040	GDC-10 2D 4mm x 10cm	TBD
M00334251540	GDC-10 2D 5mm x 15cm	TBD
M00334262040	GDC-10 2D 6mm x 20cm	TBD
M00334272540	GDC-10 2D 7mm x 25cm	TBD
M00334283040	GDC-10 2D 8mm x 30cm	TBD
M00334293040	GDC-10 2D 9mm x 30cm	TBD

GDC™-10 2D Soft SR Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M003344302SR40	GDC-10 Soft 2D SR 3mm x 2cm	TBD
M003344303SR40	GDC-10 Soft 2D SR 3mm x 3cm	TBD
M003344304SR40	GDC-10 Soft 2D SR 3mm x 4cm	TBD
M003344306SR40	GDC-10 Soft 2D SR 3mm x 6cm	TBD
M003344308SR40	GDC-10 Soft 2D SR 3mm x 8cm	TBD
M003344403SR40	GDC-10 Soft 2D SR 4mm x 3cm	TBD
M003344404SR40	GDC-10 Soft 2D SR 4mm x 4cm	TBD
M003344406SR40	GDC-10 Soft 2D SR 4mm x 6cm	TBD
M003344408SR40	GDC-10 Soft 2D SR 4mm x 8cm	TBD
M003344504SR40	GDC-10 Soft 2D SR 5mm x 4cm	TBD
M003344506SR40	GDC-10 Soft 2D SR 5mm x 6cm	TBD
M003344508SR40	GDC-10 Soft 2D SR 5mm x 8cm	TBD
M003344510SR40	GDC-10 Soft 2D SR 5mm x 10cm	TBD
M003344606SR40	GDC-10 Soft 2D SR 6mm x 6cm	TBD
M003344608SR40	GDC-10 Soft 2D SR 6mm x 8cm	TBD
M003344610SR40	GDC-10 Soft 2D SR 6mm x 10cm	TBD
M003344710SR40	GDC-10 Soft 2D SR 7mm x 10cm	TBD
M003344715SR40	GDC-10 Soft 2D SR 7mm x 15cm	TBD

GDC™-10 3D Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M00334510340	GDC-10 3D 10mm x 30cm	TBD
M00334530440	GDC-10 3D 3mm x 4cm	TBD
M00334530640	GDC-10 3D 3mm x 6cm	TBD
M00334540640	GDC-10 3D 4mm x 6cm	TBD
M00334540840	GDC-10 3D 4mm x 8cm	TBD
M00334550840	GDC-10 3D 5mm x 8cm	TBD
M00334551040	GDC-10 3D 5mm x 10cm	TBD
M00334561040	GDC-10 3D 6mm x 10cm	TBD
M00334561540	GDC-10 3D 6mm x 15cm	TBD
M00334571240	GDC-10 3D 7mm x 12cm	TBD
M00334571540	GDC-10 3D 7mm x 15cm	TBD
M00334582040	GDC-10 3D 8mm x 20cm	TBD

GDC™- 10 UltraSoft™ Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M0033432010	GDC-10 UltraSoft 2mm X 1cm	TBD
M0033432020	GDC-10 UltraSoft 2mm X 2cm	TBD
M0033432030	GDC-10 UltraSoft 2mm X 3cm	TBD
M0033432040	GDC-10 UltraSoft 2mm X 4cm	TBD
M0033432060	GDC-10 UltraSoft 2mm X 6cm	TBD
M0033432520	GDC-10 UltraSoft 2.5mm X 2cm	TBD
M0033432530	GDC-10 UltraSoft 2.5mm X 3cm	TBD
M0033432540	GDC-10 UltraSoft 2.5mm X 4cm	TBD
M0033432560	GDC-10 UltraSoft 2.5mm X 6cm	TBD
M0033433040	GDC-10 UltraSoft 3mm X 4cm	TBD
M0033433060	GDC-10 UltraSoft 3mm X 6cm	TBD
M0033433080	GDC-10 UltraSoft 3mm X 8cm	TBD
M0033434040	GDC-10 UltraSoft 4mm X 4cm	TBD
M0033434060	GDC-10 UltraSoft 4mm X 6cm	TBD
M0033434080	GDC 10-UltraSoft 4mm X 8cm	TBD

GDC™-18 Standard Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M00335010340	GDC-18 Standard 10mm x 30cm	TBD
M00335012340	GDC-18 Standard 12mm x 30cm	TBD
M00335014340	GDC-18 Standard 14mm x 30cm	TBD
M00335016340	GDC-18 Standard 16mm x 30cm	TBD
M00335018340	GDC-18 Standard 18mm x 30cm	TBD
M00335020340	GDC-18 Standard 20mm x 30cm	TBD
M00335051540	GDC-18 Standard 5mm x 15cm	TBD
M00335052040	GDC-18 Standard 5mm x 20cm	TBD
M00335062040	GDC-18 Standard 6mm x 20cm	TBD
M00335073040	GDC-18 Standard 7mm x 30cm	TBD
M00335082040	GDC-18 Standard 8mm x 20cm	TBD
M00335083040	GDC-18 Standard 8mm x 30cm	TBD
M00335091540	GDC-18 Standard 9mm x 15cm	TBD
M00335093040	GDC-18 Standard 9mm x 30cm	TBD

GDC™-18 Soft Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M00335120440	GDC-18 Soft 2mm x 4cm	TBD
M00335120840	GDC-18 Soft 2mm x 8cm	TBD
M00335130440	GDC-18 Soft 3mm x 4cm	TBD
M00335130840	GDC-18 Soft 3mm x 8cm	TBD
M00335140640	GDC-18 Soft 4mm x 6cm	TBD
M00335141040	GDC-18 Soft 4mm x 10cm	TBD
M00335150840	GDC-18 Soft 5mm x 8cm	TBD
M00335151240	GDC-18 Soft 5mm x 12cm	TBD
M00335161040	GDC-18 Soft 6mm x 10cm	TBD
M00335161540	GDC-18 Soft 6mm x 15cm	TBD

GDC™-18 2D Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M00335210340	GDC-18 2D 10mm x 30cm	TBD
M00335212340	GDC-18 2D 12mm x 30cm	TBD
M00335214340	GDC-18 2D 14mm x 30cm	TBD
M00335216340	GDC-18 2D 16mm x 30cm	TBD
M00335218340	GDC-18 2D 18mm x 30cm	TBD
M00335220340	GDC-18 2D 20mm x 30cm	TBD
M00335252040	GDC-18 2D 5mm x 20cm	TBD
M00335262040	GDC-18 2D 6mm x 20cm	TBD
M00335273040	GDC-18 2D 7mm x 30cm	TBD
M00335283040	GDC-18 2D 8mm x 30cm	TBD
M00335293040	GDC-18 2D 9mm x 30cm	TBD

GDC™-18 3D Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M00335510340	GDC-18 3D 10mm x 30cm	TBD
M00335512340	GDC-18 3D 12mm x 30cm	TBD
M00335514340	GDC-18 3D 14mm x 30cm	TBD
M00335516340	GDC-18 3D 16mm x 30cm	TBD
M00335518340	GDC-18 3D 18mm x 30cm	TBD
M00335520340	GDC-18 3D 20mm x 30cm	TBD
M00335561540	GDC-18 3D 6mm x 15cm	TBD
M00335582540	GDC-18 3D 8mm x 25cm	TBD

GDC™-18 Fibered VortX™ Detachable Coil

UPN	Description	First Batch Labeled as Stryker Neurovascular
M00335302340	GDC-18 Fibered VortX 2mm x 3mm	TBD
M00335302440	GDC-18 Fibered VortX 2mm x 4mm	TBD
M00335302540	GDC-18 Fibered VortX 2mm x 5mm	TBD
M00335302640	GDC-18 Fibered VortX 2mm x 6mm	TBD