DECLARATION OF CONFORMITY

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

Manufacturing Site(s): Stryker Neurovascular
4870 West 2100 South
Salt Lake City, UT 84120
USA

EU Authorized Representative: Stryker European Operations B.V.
Herikerbergweg 110
Amsterdam
1101 CM
Netherlands

Product: Balloon Guide Catheters
Design Dossier, NV00022353

Product Category: Intravascular occluding catheter
GMDN code: 32584

Classification: Class III, rule 7 (first indent) 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: LNE/G-MED
1 rue Gaston Boissier
75724 Paris Cedex 15
France
CE Marking No: 0459

First issued 28 August 2017

EC Certificate: Certificate # 33895
First issued 26 January 2018

DE Certificate: Certificate # 34042
First issued 26 February 2018

This Declaration of Conformity is issued under the sole responsibility of Stryker Neurovascular.

Signature, Date of Issue:

Signature: [Signature]
Name: Katherine Mack
Title: Senior Director of Quality
Stryker Neurovascular, Fremont, CA

Date: [Mar. 1, 2018]

Signature: [Signature]
Name: Angelica Beckmann
Title: Director of Regulatory Affairs
Stryker Neurovascular, Fremont, CA

Date: [03/01/2018]
Balloon Guide Catheters:

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<thead>
<tr>
<th>UPN</th>
<th>Device Description</th>
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<tbody>
<tr>
<td>90072</td>
<td>Concentric Balloon Guide Catheter, 7F</td>
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<tr>
<td>90073</td>
<td>Merci Balloon Guide Catheter, 8F x 95cm</td>
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<td>FlowGate² BGC, 8F x 95cm</td>
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<td>FlowGate² BGC, 8F x 85cm</td>
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