# EC Design Examination Certificate
## Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

**HAS EXAMINED THE DESIGN DOSSIER**
**Submitted by**

# Brivant Ltd

**Parkmore West Business Park**
**Galway**
**Ireland**

***For Product Family***

## Cardiac and Peripheral Guidewires

## GMDN Code: 35094, 58115

**CONCLUSION of EXAMINATION:**

*NSAI have performed an examination of the design dossier relating to the above named product family and conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex II (4)*

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|---|---|
| **Registration Number:** | **252.569** |
| **Original Approval:** | **5 March 2003** |
| **Last Amended on:** | **4 March 2020** |
| **Remains valid until:** | **26 May 2024** |

**Signed:**

Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

**CONDITIONS OF VALIDITY:**

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner. Approved model numbers are included in the associated attachment**

Note: Not valid without a valid Annex II Section 3 Certificate.

Changes which could affect conformity with the essential requirements of Directive 93/42/EEC or with the conditions prescribed for use of the product must receive further approval from NSAI.

**National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**