



Quality System Approval 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)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Biosensors Europe

**Rue de Lausanne 29
1110 Morges
Switzerland**

to the Product Family

**Drug-eluting coronary artery stent system, bioabsorbable-polymer
coated (BioMatrix™ Alpha, LUMENO™ Alpha)**

GMDN Code: 58771

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex
II, excluding (4)*

*The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product family is hereby authorised.*

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|-----------------------------|-------------------------|
| Registration Number: | 252.954 |
| Original Approval: | 27 November 2015 |
| Last Amended on: | 04 November 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

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

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