

# CERTIFICATE

Number: 2128896

The management system of:

**Biosensors International Group, Ltd.**

c/o Biosensors Europe SA  
Rue de Lausanne 29  
1110 Morges,  
Switzerland

including the implementation meets the requirements of the standard:

## EN ISO 13485:2016

Scope:

Design, manufacturing, storage, warehousing and distribution of:

- PTCA catheters and accessories;
- Drug eluting coronary stent systems;
- Drug coated coronary stent systems;
- Coronary stent systems;

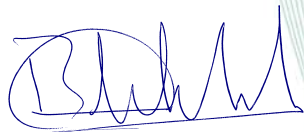
Including purchase and resale of vascular devices and accessories for coronary and peripheral applications.

Distribution of Drug eluting balloons for coronary and peripheral applications.

This certification also includes the location(s) as identified on the addendum belonging to this certificate.

Certificate expiry date: 1 October 2021  
Certificate effective date: 18 November 2018  
Certified since: 1 October 2009

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed





# ADDENDUM 1/2

To certificate: 2128896

The management system of:

## Biosensors International Group, Ltd.

List of additional certified locations

Location	Certification scope / Activity
Biosensors Interventional Technologies Pte Ltd. 36 Jalan Tukang Singapore 619266 Singapore	Design, manufacturing, storage, warehousing and distribution of: <ul style="list-style-type: none"><li>• PTCA catheters and accessories;</li><li>• Drug eluting coronary stent systems;</li><li>• Drug coated coronary stent systems;</li><li>• Coronary stent systems;</li></ul> Including purchase and resale of vascular devices and accessories for coronary and peripheral applications.  Distribution of Drug eluting balloons for coronary and peripheral applications.
Biosensors BV Arnoudstraat 8 2182 DZ Hillegom The Netherlands	Storage, warehousing and distribution of: <ul style="list-style-type: none"><li>• Vascular accessories for coronary and peripheral applications;</li><li>• Coronary stent systems;</li><li>• Drug eluting coronary stent systems;</li><li>• Drug coated coronary stent systems;</li><li>• Drug eluting balloons for coronary and peripheral applications;</li><li>• PTCA catheters and accessories.</li></ul>
Biosensors Europe SA Rue de Lausanne 29 1110 Morges, Switzerland	Design, manufacturing and distribution of: <ul style="list-style-type: none"><li>• Drug eluting coronary stent systems;</li><li>• Drug coated coronary stent systems;</li><li>• Coronary stent systems;</li><li>• PTCA catheters and accessories;</li></ul> Including purchase and resale of vascular devices and accessories for coronary and peripheral applications  Distribution of Drug eluting balloons for coronary and peripheral applications.

Addendum initial date: 1 October 2009  
Addendum effective date: 18 November 2018