

# CERTIFICATE

Number: 2128896

The management system of:

**Biosensors International Group Ltd.**

Rue de Lausanne 29  
1110 Morges,  
Switzerland

including the implementation meets the requirements of the standard:

## EN ISO 13485:2012

Scope:

Design, manufacturing, storage, warehousing and distribution of:

- PTCA catheters and accessories;
- Drug eluting coronary and peripheral stent systems;
- Drug coated coronary stent systems;
- Drug eluting coronary bifurcation stent systems;
- Coronary stent systems;
- Thermolulution, Pulmonary Artery, Central Venous, Embolectomy devices and Bipolar Pacing Catheters, Pressure Monitoring Systems

Distribution of Drug eluting balloons for coronary and peripheral applications.

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

Manufacturing, storage, warehousing, distribution, installation and servicing of Spect imaging system for cardiac applications.

Assembly and distribution of Angiographic Kits and Surgical Procedure Set for Catheter Introduction.

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

Certificate expiry date: 1 October 2018

Certificate effective date: 1 October 2015

Certified since: 1 October 2009

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
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	<p>Design, manufacturing, storage, warehousing and distribution of:</p> <ul style="list-style-type: none"><li>• PTCA catheters and accessories;</li><li>• Drug eluting coronary and peripheral stent systems;</li><li>• Drug coated coronary stent systems;</li><li>• Drug eluting coronary bifurcation stent systems;</li><li>• Coronary stent systems;</li></ul> <p>Including purchase and resale of vascular devices and accessories for coronary and peripheral applications. Distribution of Drug eluting balloons for coronary and peripheral applications.</p> <p>Manufacturing, storage, warehousing, distribution, installation and servicing of Spect imaging system for cardiac applications.</p>
Biosensors International BV. Arnoudstraat 8 2182 DZ Hillegom The Netherlands	<p>Storage, warehousing and distribution of:</p> <ul style="list-style-type: none"><li>• Vascular accessories for coronary and peripheral applications;</li><li>• Coronary stent systems;</li><li>• Drug eluting coronary and peripheral stent systems;</li><li>• Drug coated coronary stent systems;</li><li>• Drug eluting coronary bifurcation stent systems;</li><li>• Drug eluting balloons for coronary and peripheral applications;</li><li>• PTCA catheters and accessories.</li></ul>



# ADDENDUM 2/2

to certificate 2128896

concerning the management system of:

## Biosensors International Group Ltd.

List of additional certified locations

Location	Certification scope / Activity
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 and peripheral stent systems;</li><li>• Drug coated coronary stent systems;</li><li>• Drug eluting coronary bifurcation stent systems;</li><li>• Coronary stent systems;</li><li>• PTCA catheters and accessories;</li></ul> Distribution of Drug eluting balloons for coronary and peripheral applications.  Including purchase and resale of vascular devices and accessories for coronary and peripheral applications.
Biosensors International Pte. Ltd 36 Jalan Tukang Singapore 619266 Singapore	Design, manufacturing and distribution of Thermodilution, Pulmonary Artery, Central Venous, Embolectomy devices and Bipolar Pacing Catheters, Pressure Monitoring Systems, Assembly and distribution of Angiographic Kits and Surgical Procedure Set for Catheter Introduction.

Addendum initial date: 1 October 2009  
Addendum effective date: 1 October 2015