

## Declaration of Absence of Chemical and Biological Materials

We, Biosensors Europe SA, a company organized and existing under the laws of Switzerland and having its registered office at rue de Lausanne 29, 1110 Morges, Switzerland – a company of the Biosensors International Group, hereby declare that the products designated below:

**Gazelle™** Coronary Stent System

**Powerline™** PTCA Catheter

**BioMatrix Flex™** Drug Eluting Coronary Delivery System

**BioMatrix™** Drug Eluting Coronary Delivery System

**Axxess™** Drug Eluting Coronary Bifurcation Stent System

do not contain any chemical and biological materials listed below:

Chemical	Biological
<ul style="list-style-type: none"> <li>• Substance of very high concern (SVHC) listed in European REACH ordinance of chemical substance.</li> <li>• Nano-silver or colloidal silver.</li> <li>• Latex material</li> <li>• Phthalates eg. Di(2-ethylhexyl) phthalate (DEHP), Polyvinyl chloride (PVC)</li> </ul>	<ul style="list-style-type: none"> <li>• Animal origin material</li> <li>• Biological origin material</li> <li>• Blood and human plasma derivatives</li> </ul>

and meet all applicable requirements of the Medical Device Directive 93/42/EEC.

Biosensors International Group Ltd confirms that it maintains a Quality Management System according to the international recognized standard ISO 13485 and that its quality system complies to the GMP requirements as stated in the FDA regulation 21 CFR 820.

Morges, February 27<sup>th</sup>, 2012

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