



## PRESS RELEASE

# Biosensors International Announces Enrollment of First Patient in the RISE™ SC study

**Morges, Switzerland, February 4<sup>th</sup> 2022** – Biosensors International Group, Ltd. ("Biosensors" or the "Company"), a developer and manufacturer of innovative medical devices, announced today the enrollment of the first patient in the **RISE™ SC study** a single arm, prospective, multicenter First-in-Human trial to evaluate the acute safety and device success of the RISE™ SC coronary balloon when used as a dilatation device in the stenotic portion of a coronary artery or bypass graft in patients with Coronary Artery Disease. This trial is targeting CE-mark approval for the new RISE™ Semi-Compliant balloon (SCB). It will include 3 investigational centers in Switzerland led by Prof. Marco Roffi, Director of the Interventional Cardiology Unit at the University Hospital of Geneva, Switzerland and member of the ESC Committee for Practice Guidelines. The first case with this device was performed in the HVS of Sion. The first patient was a 78-year-old male with a lesion in the LAD. A 2.5x12 mm RISE™ SC balloon was used, and no complications were reported during the procedure.

Balloon angioplasty is mainly performed for the purpose of pre-dilatation/lesion preparation prior to coronary stenting, followed by post-dilatation to optimize stent expansion. The goal of lesion preparation is to facilitate stent delivery and expansion. In some patients, direct stenting without pre-dilatation can be performed, but pre-dilatation is mandatory in severely stenotic lesions. In most PCI procedures, pre-dilatation is performed using Semi-Compliant (SC) balloons at moderate pressure (8-10 atm) as they have a lower crossing profile than Non-Compliant (NC) balloons.

The RISE™ SC balloon has been designed and developed to improve trackability and crossing profile and is aimed at having comparable performance to currently available "best-in-class" SC balloons.

With this new device, Biosensors continues investing in its cardiovascular products portfolio. With more than 20 years of experience working with coronary stents and balloons, the company is expanding their own balloon portfolio and as a result they have already launched their Non-Compliant Balloon (NCB) RISE™ NC. The RISE™ SC balloon will be a great addition to the RISE™ family of balloons.

### **About Bluesail Medical and Biosensors**

Bluesail Medical Co., Ltd. is a subsidiary of the Bluesail Group and represents its medical industrial arm. Founded in 2002 as a China Mainland-Hong Kong joint venture enterprise (former Shandong Blue Sail Plastic & Rubber Co., Ltd); and successfully listed on the Shenzhen Stock Exchange on April 2, 2010 (stock code 002382). Bluesail Medical has two primary business divisions: protective and sanitary products and

cardiovascular and neurovascular devices. Protective and sanitary products are manufactured in Asia and Greater China region. Its sales network covers over 100 different countries and regions in North and South America, Europe, Oceania, and other regions. These products constitute 22% of the global market share and since 2012, Bluesail Medical has become the leading enterprise in this industry. The cardiovascular and neurovascular devices business is undertaken by its subsidiary Biosensors which was formed in 1990. Biosensors has production centers in Singapore and China. Its products are sold in over 90 countries and regions. It is one of the top four companies engaged in the research and development, manufacturing and sales of devices used during percutaneous coronary intervention.

For more information about Bluesail Medical, please visit <http://www.bluesail.cn/en/index.php>

For more information about Biosensors International, please visit <http://www.biosensors.com>

### **Forward-Looking Statements**

Certain statements herein include forward-looking statements which generally can be identified by the use of forward-looking terminology, such as “may,” “will,” “expect,” “intend,” “estimate,” “anticipate,” “believe,” “project” or “continue” or the negative thereof or other similar words. All forward looking statements involve risks and uncertainties, including, but not limited to, customer acceptance and market share gains, competition from companies that have greater financial resources; introduction of new products into the marketplace by competitors; successful product development; dependence on significant customers; the ability to recruit and retain quality employees as Bluesail Medical and Biosensors grow; and economic and political conditions globally. Actual results may differ materially from those discussed in, or implied by, the forward-looking statements. The forward-looking statements speak only as of the date of this release and Bluesail Medical or Biosensors assumes no duty to update them to reflect new, changing or unanticipated events or circumstances.

RISE is trademark of Biosensors International Group, Ltd.

The RISE™ SCB is an investigational device and is not available for sale in any country.