CE EC Declaration of Conformity

(Medical devices Directive 93/42/EEC as amended by Directive 2007/47 /EC Dec. -Lei 145/2009 of 17th June)

Manufacturer: **BASTOS VIEGAS S.A. Av. da Fábrica nº298, 4560-164 Guilhufe, Penafiel, Portugal**
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Medical devices:

Description	Brand
Tongue depressor, sterile	Zillion®

Classification: **Class Is, rule 5 according to annex IX of the Medical Devices Directive 93/42/EEC as amended by Medical Devices Directive 2007/47/EC**

Conformity assessment: According to Annex V of Medical Devices Directive 93/42/EEC as amended by Medical Devices Directive 2007/47/EC

Under the supervision of the Notified body: **SGS, Belgium NV – NOTIFIED BODY 1639**
Address: SGS House, Noorderlaan 87, 2030 Antwerpen, Belgium

EC certificate number: **ES19/86752 - Annex V**

Declares:

- That the medical devices referred above fulfill the essential requirements established in Annex I of Medical Devices Directive 93/42/EEC of 14 th June as amended by Medical Devices Directive 2007/47/EC and Dec.-Lei 145/2009 of 17 th June, so they do not compromise the clinical state nor the safety of the patients, nor the safety and the health of the users or, eventually, third parties when used in the proper conditions and according with its intended use, considering that the eventual risks associated to the final purposes are acceptable risks considering the benefits to the patients and they are compatible with a high level of safety and low risk to the patient.
- Medical devices referred above fulfill applicable harmonized standards to be in compliance with the essential requirements of Medical Devices Directive: EN ISO 13485:2016/AC:2018; EN ISO 15223-1:2016; EN 1041:2008; EN ISO 14971:2012; EN ISO 10993-1:2009/AC:2010; EN ISO 10993-7:2008/AC:2009; EN 556-1: 2001/AC:2006; EN ISO 11607-1:2009; EN ISO 11607-2:2006; EN ISO 11737-2:2009;
Other applicable standards: ISO 11135:2014; EN 1041:2008+A1:2013; EN ISO 10993-1:2018; EN ISO 11607-1:2017; EN ISO 11607-2:2017;
- This declaration is issued under the sole responsibility of the manufacturer.

It is committed:

- To create and to keep updated a systematic analysis process of the achieved experience in post- production phase, including the requirements of Medical Devices Directive 93/42/EEC of 14 th June as amended by Medical Devices Directive 2007/47/EC and Dec.-Lei 145/2009 of 17 th June, annex XVI.
- To develop proper ways for application of any necessary corrective actions, having in mind the nature and the risks related with the product, and to notify the Competent Authority of its incidents, such as:
- Any dysfunction, damage or deterioration in the features or functional behavior of the device, as well in any inadequacy , default or insufficient labeling or instructions of use of the device, which might lead or might had lead to death or serious deterioration of patient health state, users or third part;
- Any indirect damage, as in consequence of a wrong medical decision, related to the medical device, when used in accordance with the instructions of use supplied by the manufacturer;
- Any technical or medical reason related with the features or the functional behavior of a device that, for the reasons stated in previous sentences, lead to a corrective safety action in the Portuguese market, including the same type devices produced by the manufacturer;
- Other information that the experience demonstrates necessary to communicate.
- To prepare the technical documentation and to keep it updated, including this declaration, keeping it available to the Competent Authority, for inspection purposes, during five years after the medical device last production date.

Bastos Viegas S.A. Quality Management system Sistema de gestão da qualidade

Assuntos Regulamentares/ Regulatory affairs	Direcção Técnica/ Technical Director	Um Administrador/ Managing Director
Fátima Sá Couto	*Gisela Mendes*	*Luis Guimarães*