EC Certificate Production Quality Assurance System: Certificate GB13/88103

The management system of

BASTOS VIEGAS, S.A.

Avenida da Fábrica, GUILHUFE, PENAFIEL, 4560-164, Portugal

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

For the following products

Orthopedic padding, elastic and tubular bandages.
Absorbent dressings and pads for wound care, eye care and disinfection.
Sterile, single use, non-invasive forceps, umbilical cord clamps, disinfectant applicators and towel clamps.
Sterile, single use, tongue depressors, Ayre spatula, cervical brush.
Sterile, single use, surgical drapes, surgical clothing, operation room towels, incise drapes, instrument pouches, fluid pouches, surgical skin marker, tube holders, adhesive tape for operations, surgical absorbent pads and draping sets.
Sterile, single use, protection blankets to patients on emergencies and baby blankets.
Sterile, single use, absorbent cotton applicators and products for absorption and sampling of exudates from body orifices, fluids from wounds and application of disinfectants. Procedure and protection sets.
Sterile medicine cups for liquid medicine administration in the body.

This certificate is valid from 10 August 2015 until 31 October 2015
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 October 2015
Issue 6. Certified since 21 February 2013

Certification is based on reports numbered GB/PI 229304

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
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SGS CE 18 0811

Direktė
Jūratė Valinskaitė

2015-10-13

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Translation in English from the Portuguese original

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
Tel.: +351 255 729 500 • Fax: +351 255 729 501 • Email: geral@bastosviegas.com • www.bastosviegas.com

Medical devices:

Procedure sets, sterile	
Composed by:	**- cellulose swabs; cotton balls; absorbent pads; wrapping field; sterilization crepe paper in sheets;** **- orthopaedic padding natural; elastic crepe bandages and elastic bandages;** **- non-woven strips adhesive tape; adhesive spots for gallipots;** **- rectangular and round gallipots; ring basin; plastic trays and emesis basin;** **- medical applicators**

Classification: Class IS, Rule 1 according to annex IX of the Medical Devices Directive 93/42/EEC as amended by Medical Devices Directive 2007/47/EC

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

Notified body: SGS, UK – NOTIFIED BODY 0120
Address: Unit 202B, Worle Parkway, Weston Super Mare BS22 OWA, United Kingdom

EC certificate number: GB13/88103

Declares:

- That the medical devices referred above fulfill the essential requirements established in Annex I of Medical Devices Directive 93/42/EEC of 14th June as amended by Medical Devices Directive 2007/47/EC and Dec.-Lei 145/2009 of 17th 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 highly suitable with health and safety protection.
- That the production of medical devices referred above fulfill with the following harmonized norms to be in compliance to the essential requirements of Medical Devices Directives:
  EN 980; ISO 15223-1; EN 1041; EN ISO 14971; EN ISO 11737-1; ISO/TR 15499; EN ISO 10993-1; EN 556-1; EN ISO 11607-1; EN ISO 11607-2; EN ISO 11737-2;
  And additionally for devices sterilized by ethylene oxide:
  EN 1422; EN ISO 11135-1; EN ISO 10993-7;
  And additionally for devices sterilized by moist heat:
  EN 285; EN ISO 17665-1; ISO/TS 17665-2;
- Other applicable norms:
  EN ISO 13485:2012; EN ISO 9001:2008

It is committed:

- To create and to keep updated a systematic analysis process of the achieved experience in post- production phase, including the requirements related in annex XVI, of the Dec.-Lei 145/2009, 17th June.
- 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

Direktorė Jūratė Valinskaitė

Regulatory Affairs	Technical Director	Managing Director
Fátima Sá Couto	*Gisela Mendes*	*Luis Guimarães*

REV: 08

Penafiel, 29/04/2014

Bastos Viegas

TO WHOM WHO IT MAY CONCERN

We, **BASTOS VIEGAS, S.A.,** a duly established company at Guilhufe, Penafiel, Portugal, hereby declare that

UAB,, AMV PROJECT"

Is authorized to offer and distribute our products, in a non-exclusive basis in Lithuania market.

This declaration refers exclusively to Bastos Viegas products presented in their original packing, with Bastos Viegas standard layout and duly supported by technical documents of Bastos Viegas S.A., catalogue or leaflets.

Penafiel, 16th September 2015

Bastos Viegas,S.A.
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Direktorė
Jūratė Valinskaitė

LIETUVOS RESPUBLIKA UAB "AMV Project" Nr.1

2015 -10- 13

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