

EC Certificate Production Quality Assurance System: Certificate GB13/88103

The management system of

BASTOS VIEGAS, S.A.

Avenida da Fábrica, GUILHUFÉ, 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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 02 November 2015 until 31 July 2020
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 June 2018

Issue 7. Certified since 21 February 2013

Certification is based on reports numbered GB/PI 229304

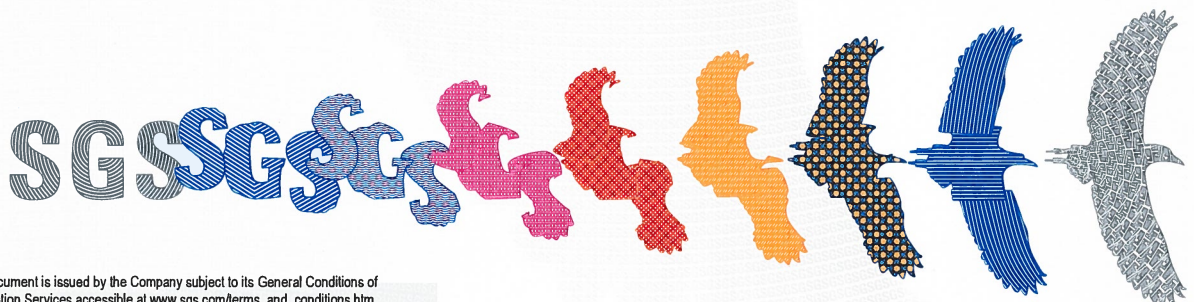
Authorised by

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BASTOS VIEGAS, S.A.

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and
maintaining sterile conditions.

Issue 7

Detailed scope

- Sterile, single use non-invasive non-woven dressings.**
- Sterile single use skin staple remover.**
- Sterile, single use orthopedic padding, elastic and tubular bandages.**
- Sterile, single use non-adherent wound dressings.**
- Sterile, single use absorbent pads, maternity pads and first aid dressings.**
- Sterile, single use non-invasive, gauze dressings, eye pads, cotton dressings
and cellulose swabs.**
- Sterile, single use non-invasive forceps and umbilical cord clamps.**
- Sterile, single use tongue depressor.**
- Sterile, single use Ayre spatula and cervical brush.**
- Sterile, single use surgical drapes, surgical clothing and draping sets.**
- Sterile, single use operating room towels, towel clamps, incise drapes,
instrument pouches, fluid pouches, surgical skin marker, tube holders,
adhesive tape for operations and surgical absorbent pads.**
- Sterile, single use protection blankets for patients in emergencies
and baby blankets.**
- Sterile, single use absorbent cotton applicators for absorption
and sampling of exudates from body orifices and wounds.**
- Sterile, single use disinfectant applicators.**
- Sterile, single use protection sets including gowns, hats,
shoe covers, gloves and masks.**
- Sterile, single use procedure sets.**
- Material de penso de não-tecido, estéril não-invasivo.**
- Removedor de agrafos, estéril e de uso único.**
- Ligaduras ortopédicas, elásticas e tubulares, estéreis e de uso único.**
- Material de penso não-aderente estéril e de uso único.**
- Pensos absorventes, pensos de maternidade e compressas de primeiros
socorros estéreis e de uso único.**
- Material de penso de gaze não-invasivo, pensos oftálmicos, material de penso
de algodão e compressas de celulose, estéreis e de uso único.**
- Pinças não-invasivas e clamp umbilical, estéreis e de uso único.**
- Abaixa-línguas estéril e de uso único.**
- Espátula d'Ayre e escova de recolha endocervical, estéreis e de uso único.**
- Campos cirúrgicos, roupa cirúrgica e sets de cobertura, estéreis e de uso único.**
- Toalha de bloco operatório, clamp de campos, campos de incisão,
bolsas de instrumentos, bolsas de recolha de fluidos,
marcador cirúrgico, segura-tubos, adesivo para
operações e almofada absorvente cirúrgica, estéreis e de uso único.**
- Lençol de protecção para pacientes em situação de emergência
e lençol de bebé, estéreis e de uso único.**