



EC Certificate Production Quality Assurance System: Certificate ES19/86752

The management system of

BASTOS VIEGAS, SA

Avenida da Fábrica; 298
4560-164 Guilhufe-Penafiel. 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 16 December 2019 until 31 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 21 February 2013
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered ES/MAD 228876

Authorised by

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BASTOS VIEGAS, SA

Directive 93/42/EEC

on medical devices, Annex V

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

Issue 1

Detailed scope

- Sterile, single use non-invasive non-woven dressings.**
- 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.**
- Sterile, single use non-invasive forceps, and umbilical cord clamps.**
- Sterile, single use tongue depressor.**
- Sterile, single use Ayre spatula.**
- Sterile, single use, eye shield.**
- Sterile, single use surgical drapes and draping sets.**
- Sterile, single use operating room towels, towel clamps, incise drapes, instrument pouches, fluid pouches, 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 disinfectant applicators.**
- Sterile, single use procedure sets.**
- Sterile single use plastic skin staple remover.**
- Sterile single use guidewire bowls for preparation and temporary storage of guidewire while keeping it in place and hydrated.**

- Material de penso de não-tecido, não-invasivo, 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.**
- Penso absorventes, penso de maternidade e compressas de primeiros socorros estéreis e de uso único.**
- Material de penso de gaze não-invasivo, penso oftálmico estéril 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 estéreis e de uso único.**
- Protector ocular estéril e de uso único.**
- Campos cirúrgicos 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, 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.**
- Aplicadores para desinfeção estéreis e de uso único.**
- Sets de procedimento, estéreis e de uso único.**
- Removedor de agrafo plástico, estéril e de uso único.**
- Recipiente fio-guia estéril e de uso único, destinado à preparação e armazenamento temporário do fio-guia, mantendo-o na sua posição e hidratado.**