

EC Certificate Full Quality Assurance System: GB13/88104

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 II (excluding Section 4)

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 4. Certified since 21 February 2013

Certification is based on reports numbered GB/PI 229304

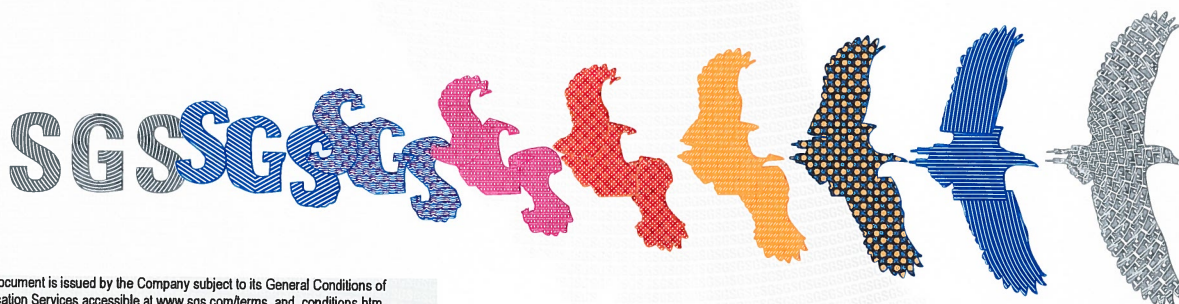
Authorised by

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Page 1 of 2



BASTOS VIEGAS, S.A.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 4

Detailed scope

**Sterile and non-sterile, single use non-woven dressings,
with or without X-Ray thread.**

**Sterile single use surgical instruments including single use surgical
forceps and single use surgical scissors for invasive surgeries.**

**Sterile and non-sterile, single use gauze dressings,
with or without X-Ray thread.**

Sterile, single use knitted viscose dressings.

**Sterile and non-sterile single use stylet intended to monitor and
explore wounds and sterile and non-sterile single use curette
intended for scarping, debriding and/or cleaning
of biological tissues and wounds.**

Sterile, single use surgical and procedure sets and packs.

**Procedure packs for general surgical procedures which
include sutures and/or electrosurgical pencils.**

Sterile, single use foam dressings.

**Material de penso e cirúrgico de não-tecido, com e sem fio raio-X,
estéril e não-estéril e de uso único.**

**Instrumentos cirúrgicos estéreis incluindo pinças cirúrgicas de uso
único e tesouras cirúrgicas de uso único para cirurgias invasivas.**

**Material de penso e cirúrgico de gaze, com e sem fio raio-X,
estéril e não-estéril e de uso único.**

Penso de malha de viscose estéril e de uso único.

**Estilete indicado para monitorizar e explorar feridas e cureta indicada para
raspar, desbridar e/ou limpar tecidos biológicos e feridas.**

Sets e packs cirúrgicos e de procedimento, estéreis e de uso único.

Sets e Packs cirúrgicos que incluem suturas e/ou bisturis eléctricos.

Penso de espuma estéril e de uso único.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market