

EC Certificate Full Quality Assurance System: Certificate ES19/86750

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 II (excluding Section 4)

For the following products The scope of registration appears on page 2 of this certificate

This certificate is valid from 24 May 2021 until 31 July 2023 and remains valid subject to satisfactory surveillance audits. Issue 3. Certified since 21 February 2013.

Certification is based on reports numbered ES/MAD 228876

Authorised by

mater

Global Medical Devices Head of Notified Body SGS Belgium NV, Notified Body 1639 SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

Page 1 of 2



- This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms\_and\_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at https://www.sgs.com/encertified-clients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be proceeding to the live of the live of the live of the false of the live of t offenders may be prosecuted to the fullest extent of the law.



Certificate ES19/86750 continued

## BASTOS VIEGAS, SA Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

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

Sterile and non-sterile, single use gauze dressings, with or without X-Ray thread. Sterile and non-sterile single use plastic instruments: stylet intended to monitor and explore wounds; curette intended for scraping, debriding and/or cleaning of biological tissues and wounds; needle-holders intended to hold and guide suture needles securely for suturing; roux retractor intended to hold back tissues and organs, in order to expose the surgical field; invasive forceps for surgical procedures.

> Sterile, single use surgical and procedure sets and packs. Sterile, single use foam dressings.

Sterile and non-sterile, single use surgical bowls, trays, basin, basin liner, pitcher, lids and bowl sets for temporary storage and transport of organs and tissues during surgical procedures.

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

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

Instrumentos plásticos estéreis e não estéreis de uso único: estilete destinado a monitorar e explorar feridas; cureta destinada à raspagem, desbridamento e / ou limpeza de tecidos biológicos e feridas; porta-agulhas destinados a segurar e orientar as agulhas de sutura de forma segura durante a sutura; afastador roux destinado à exposição de tecido e órgãos, permitindo a visualização do local operatório; pinças invasivas para procedimentos cirúrgicos. Sets e packs cirúrgicos e de procedimento, estéreis e de uso único.

Penso de espuma estéril e de uso único.

Recipientes, tabuleiros, bacia, cobertura de bacia, jarros, tampas e sets de recipientes cirúrgicos, estéreis e não estéreis e de uso único para armazenamento temporário e transporte de orgãos e tecidos durante procedimentos cirúrgicos.

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.

Page 2 of 2

This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms and, conditions.thm: Attention is drawn to the limitations of liability, Indemnification and jurisd This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms\_and\_conditions.thm: Attention is drawn to the limitations of liability, indemnification and jurisd