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 24 May 2021 until 31 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 21 February 2013.

Certification is based on reports numbered ES/MAD/ 228876

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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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 2

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, 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.
Pensos absorventes, pensos de maternidade e compressas de primeiros socorros estéreis e de uso único.
Material de penso de gaze não-invasivo, pensos oftálmicos estéreis e de uso único.
Pinças não-invasivas e clamp umbilical, estéreis e de uso único.
Abaixa-línguas estéril 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 fluídos, 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 desinfecção estéreis e de uso único.
Sets de procedimento, estéreis e de uso único.
Removedor de agrafos 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.

Bastos Viegas S.A.
Avenida da Fábrica, 298,
4560-164
Guilhufe-Penafiel.
Portugal

01st September 2023

Confirmation Letter Reference: CLNB1639 - ES/MAD/300002696

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Bastos Viegas S.A.
Avenida da Fábrica, 298,
4560-164
Guilhufe-Penafiel.
Portugal
SRN: PT-MF-000002795 + PT-PT-000002808 + PT-IM-000002801

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

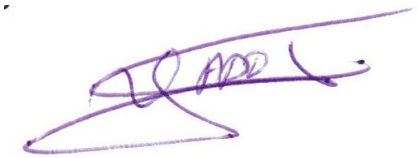
- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices

- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,



pp [Jérôme JADOT]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name	MDR Device classification & name	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile and non-sterile, single use non-woven dressings, with or without X-Ray thread.	Class IIa: Sterile and non-sterile, single use, invasive, nonwoven dressings, with or without X-Ray thread.	N/A	Certificate ES19/86750; NB1639
	Class IIa: Sterile and non-sterile, single use, invasive, texart dressings.		
Sterile and non-sterile, single use gauze dressings, with or without X-Ray thread.	Class IIa: Sterile and non-sterile, single use, invasive gauze dressings, with or without X-Ray thread.	N/A	Certificate ES19/86750; NB1639
	Class IIa: Sterile and non-sterile, single use, ribbon gauze dressings.		
	Class IIa: Sterile and non-sterile, single use, vaginal tampons.		
Sterile and non-sterile single use plastic instruments: stylet intended to monitor and explore wounds; curette intended for scraping, debriding and/or cleaning of	Class IIa: Sterile and non-sterile, single use, stylet.	N/A	Certificate ES19/86750; NB1639
	Class IIa: Sterile and non-sterile, single use, curettes.		
	Class IIa:		

Device name	MDR Device classification & name	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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 and non-sterile, single use, needle holders.		
	Class IIa: Sterile and non-sterile, single-use, retractors.		
	Class IIa: Sterile and non-sterile single use haemostatic forceps.		
	Class IIa: Sterile and non-sterile, single use, auxiliary forceps.		
	Class IIa: Sterile and non-sterile, single-use, standard forceps.		
	Class IIa: Sterile and non-sterile, single-use, sponge forceps.		
	Class IIa: Sterile and non-sterile, single-use, kocher forceps.		
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.	Class IIa: Sterile and non-sterile, single use, surgical bowls, trays, basins, basin liners, pitchers and lids.	N/A	Certificate ES19/86750; NB1639
	Class III: Sterile, single use, procedure packs.	N/A	Certificate ES19/86750; NB1639
Sterile, single use surgical and procedure sets and packs.	Class III: Sterile, single use, procedure packs.	N/A	Certificate ES19/86750; NB1639
Sterile, single use procedure sets		N/A	Certificate ES19/86752; NB1639

Device name	MDR Device classification & name	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile, single use non-invasive non-woven dressings.	Class Is: Sterile, single use, non-invasive, nonwoven dressings.	N/A	Certificate ES19/86752; NB1639
Sterile, single use orthopedic padding, elastic and tubular bandages.	Class Is: Sterile, single use, orthopaedic paddings.	N/A	Certificate ES19/86752; NB1639
	Class Is: Sterile, single use, conforming bandages.		
	Class Is: Sterile, single use, support bandages.		
	Class Is: Sterile, single use, crepe bandages.		
	Class Is: Sterile, single use, short stretch bandages.		
	Class Is: Sterile, single use, stockinettes.		
Sterile, single use non-adherent wound dressings.	Class Is: Sterile, single use, non-adherent dressings.	N/A	Certificate ES19/86752; NB1639
Sterile, single use absorbent pads, maternity pads and first aid dressings.	Class Is: Sterile, single use, absorbent pads.	N/A	Certificate ES19/86752; NB1639
	Class Is: Sterile, single use, maternity pads.		
	Class Is: Sterile, single use, first-aid dressings.		
Sterile, single use non-invasive, gauze dressings, eye pads.	Class Is: Sterile, single use, eye pads.	N/A	Certificate ES19/86752; NB1639
	Class Is:		

Device name	MDR Device classification & name	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	Sterile, single use, gauze bandages.		
Sterile, single use, non-invasive forceps and umbilical cord clamps.	Class Is: Sterile, single-use, non-invasive forceps, towel clamps and tube clamps.	N/A	Certificate ES19/86752; NB1639
	Class Is: Sterile, single-use, umbilical cord clamp.	N/A	Certificate ES19/86752; NB1639
Sterile, single use, tongue depressor.	Class Is: Sterile, single use, tongue depressors.	N/A	Certificate ES19/86752; NB1639
Sterile, single use eye shield.	Class Is: Sterile, single use, eye shields.	N/A	Certificate ES19/86752; NB1639
Sterile, single use surgical drapes and draping sets.	Class Is: Sterile, single use, draping sets.	N/A	Certificate ES19/86752; NB1639
	Class Is: Sterile, single use, surgical drapes.		
	Class Is: Sterile, single use, medical equipment covers.		
Sterile, single use operating room towels, towel clamps, incise drapes, instruments pouches, fluid pouches, adhesive tape for operations and surgical absorbent pads.	Class Is: Sterile, single use, non-invasive, nonwoven and Texart OR towels and absorbent pads.	N/A	Certificate ES19/86752; NB1639
	Class Is: Sterile, single-use, non-invasive forceps, towel clamp and tube clamp.		
	Class Is: Sterile, single use, incise drapes.		
	Class Is:		

Device name	MDR Device classification & name	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	Sterile, single use, instrument and fluid pouches. Class Is: Sterile, single use, operation tape.		
Sterile, single use, protection blankets for patients in emergencies and baby blankets.	Class Is: Sterile, single use, protection sheets. Class Is: Sterile, single use, baby blankets.	N/A	Certificate ES19/86752; NB1639
Sterile, single use disinfectant applicators.	Class Is: Sterile, single use, foam applicators.	N/A	Certificate ES19/86752; NB1639
Sterile, single use plastic skin staple remover.	Class Is: Sterile, single use, skin staple remover.	N/A	Certificate ES19/86752; NB1639
Sterile, single use guidewire bowls for preparation and temporary storage of guidewire while keeping it in place and hydrated.	Class Is: Sterile, single use, guidewire bowls.	N/A	Certificate ES19/86752; NB1639
Sterile, single use, measuring medicine cups for medicine administration.	Class Is/m & class Im: Sterile and non-sterile, single use, medicine cups.	N/A	Certificate ES19/86753; NB1639
Non sterile, single use, measuring medicine cups for medicine administration.		N/A	Certificate ES19/86751; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
01/09/2023	Version 1	Initial issue