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

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

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.

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:

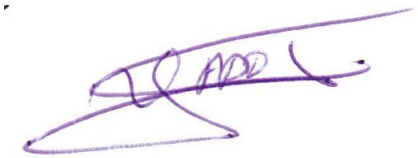
- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**BASTOS VIEGAS S.A.**
Manufacturer address and contact details	Avenida da Fábrica, nº 298 4560-164 Guilhufe Penafiel, Portugal Tel.: +351 255 729 500; Fax: +351 255 729 501 Email: geral@bastosviegas.com www.bastosviegas.com
Single Registration Number (SRN)	PT-MF-000002795

Notified body name	SGS Belgium NV □ See attached schedule
Notified body number	NB 1639 □ See attached Schedule
Directive Certificate number(s) to which this confirmation is made	ES19/86750 ES19/86751 ES19/86752 ES19/86753 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	31 July 2023 □ See attached schedule
End date of extended validity/transition period	31 December 2028 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificates** (see attached schedule) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificates** as listed above or in the attached schedule

Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards and

Expires *after* 20 March 2023:

Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024 (specifically on 24 June 2022).

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Bastos Viegas S.A.

Penafiel, 05/07/2023

Bastos Viegas S.A. Quality Management system Sistema de gestão da qualidade

Gisela Mendes
Person responsible for regulatory compliance
Manager Quality & Regulatory Affairs

Email: giselamendes@bastosviegas.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made[1]	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
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 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.	**ES19/86750**	31 July 2023	SGS Belgium NV, 1639	SGS Belgium NV, 1639	31 December 2028
Non sterile, single use, measuring medicine cups for medicine administration	**ES19/86751**	31 July 2023	SGS Belgium NV, 1639	SGS Belgium NV, 1639	31 December 2028
Sterile, single use, measuring medicine cups for medicine administration	**ES19/86753**	31 July 2023	SGS Belgium NV, 1639	SGS Belgium NV, 1639	31 December 2028

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made[1]	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
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, instruments 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	**ES19/86752**	31 July 2023	SGS Belgium NV, 1639	SGS Belgium NV, 1639	31 December 2028

[1]Certificates:

ES19/86750 issued according to the Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

ES19/86751 issued according to the Directive 93/42/EEC on medical devices, Annex V restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

ES19/86752 issued according to the Directive 93/42/EEC on medical devices, Annex V restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

ES19/86753 issued according to the Directive 93/42/EEC on medical devices, Annex V restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions, and the conformity of the devices with metrological requirements