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Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards and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