EU Quality Management System Certificate ES24/00000641

The management system of

BASTOS VIEGAS S.A.

Avenida da Fábrica, 298, 4560-164 Guilhufe - Penafiel. Portugal
SRN Number: PT-MF-000002795, PT-PR-000002808

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 07 June 2024 until 07 June 2029 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 07 December 2028

Issue 1. Certified since 07 June 2024

Authorised by
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MDR EU Quality Management System certificate (Annex IX QMS)

Issue 1

Procedure packs under article 22.
MDS1011, MDS1005 EtO; MDN1214:

Sterile, wound dressing sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255005LC]

Sterile, wound dressing sets, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255010L5]

Sterile, wound dressing sets.
[Basic UDI-DI: 56056221255011L7]

Sterile, anaesthesia procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255006LE]

Sterile, anaesthesia procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255012L9]

Sterile, general surgical procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255007LG]

Sterile, general surgical procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255013LB]

Sterile, general surgical procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255016LH]

Sterile, general surgical procedure packs/sets/kits.
[Basic UDI-DI: 56056221255017LK]

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Sterile, dental/maxillofacial surgical procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255008LJ]

Sterile, dental/maxillofacial surgical procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255014LD]

Sterile, dental/maxillofacial surgical procedure packs/sets/kits.
[Basic UDI-DI: 56056221255015LF]

Sterile, radiology procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255009LL]

Sterile, radiology procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255082LW; 56056221255083LY]

Sterile, angiography procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255018LM; 56056221255065LW; 56056221255066LY]

Sterile, irrigation sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255019LP]

Sterile, irrigation sets, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255020L8]

Sterile, orthopaedic surgical procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255021LA; 56056221255029LS; 56056221255075LZ]

Sterile, orthopaedic surgical procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255022LC: 56056221255032LF; 56056221255074LX]

Sterile, obstetrical/gynaecological surgical procedure packs/sets//kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255025LJ; 56056221255038LT]

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Sterile, obstetrical/gynaecological surgical procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255072LT]

Sterile, ENT surgical procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255024LG]

Sterile, ENT surgical procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255081LU]

Sterile, birthing/delivery procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255026LL]

Sterile, vascular surgical procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255030LB; 56056221255039LV; 56056221255040LE]

Sterile, vascular surgical procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255031LD; 56056221255042LJ]

Sterile, urological surgical procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255033LH; 56056221255035LM]

Sterile, urological surgical procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255034LK]

Sterile, urethral catheterization kits/sets, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255036LP; 56056221255044LN]

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Sterile, urethral catheterization kits/sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255037LR]

Sterile, oral care sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255041LG]

Sterile, suture sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255046LS]

Sterile, suture sets.
[Basic UDI-DI: 56056221255049LY]

Sterile, suture removal sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255050LH]

Sterile, skin staple removal sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255051LK]

Sterile, surgical patient preparation sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255052LM]

Sterile, surgical patient preparation sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255053LP; 56056221255071LR]

Sterile, haemodialysis sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255054LR]

Sterile, haemodialysis sets, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255056LV]

Sterile, compression bandaging sets, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255058LZ; 56056221255057LX]

Sterile, cardiothoracic surgical procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255061LN; 56056221255067M2]

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Sterile, cardiothoracic surgical procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255062LQ]

Sterile, nephrology procedure packs/sets/kits, with measuring function, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255064LU]

Sterile, surgical bowl, sets.
[Basic UDI-DI: 56056221255068M4]

Sterile, ophthalmology procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255085M4]

Sterile, neurosurgery procedure packs/sets/kits, intended to administer and/or remove a medicinal product.
[Basic UDI-DI: 56056221255073LV]

Class IIa devices.
MDN1208, MDS1005:

Sterile and non-sterile, single-use, stylet.
[Basic UDI-DI: 56056221201001HH, 56056221201002HK]

Sterile and non-sterile, single-use, curettes.
[Basic UDI-DI: 56056221202001HQ, 56056221202002HS]

Sterile and non-sterile, single-use, haemostatic forceps.
[Basic UDI-DI: 56056221203001HX, 56056221203002HZ]

Sterile and non-sterile, single-use, auxiliary forceps.
[Basic UDI-DI: 56056221204001J6, 56056221204002J8]

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Sterile and non-sterile, single-use, needle-holders.
[Basic UDI-DI: 56056221205001JD, 56056221205002JF]

Sterile and non-sterile, single-use, standard forceps.
[Basic UDI-DI: 56056221206001JL, 56056221206002JN]

Sterile and non-sterile, single-use, sponge forceps.
[Basic UDI-DI: 56056221207001JT, 56056221207002JV]

Sterile and non-sterile, single-use, Kocher forceps.
[Basic UDI-DI: 56056221208001K2, 56056221208002K4]

Sterile and non-sterile, single-use, retractors.
[Basic UDI-DI: 56056221209001K9, 56056221209002KB, 56056221209003KD, 56056221209004KF]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - ES/MAD/300002696 - S2A 1.1
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: N/A