Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

SRN PT PR-000002808

DRQ 14/21 REV.03 2026/06/18

Product Specification

Ref: 490-036

Alias: 490999036

Brand:

Description:	Disinfection set

STERILE EO

isento Latex free

isento PVC free

Composition:	Please see below.
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Sterilization method:	Ethylene Oxide
Shelf life:	60 months maximum. The validity of each LOT will be the shortest validity among all components used
CFU/g:	N.A.
Sterility Assur. Level_SAL:	≤10^-6



Nr and Revision Date:	59 -- 2026/09/03
CE Class:	Procedure Packs under article 22nd
CE mark:	Stated in components
Compliance with:	Reg MD/DM (EU) 2017/745
Packed and sterilized by:	Bastos Viegas s.a
Applicable standards:	EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN ISO 13485:2016 A11:2021 ; EN ISO 10993-1:2020 ; EN ISO 10993-7:2008 ; ISO 10993-7:2008 Amd1 2019 ; EN ISO 10993-18:20 AMD1:23 ; EN ISO 11737-2:2020 ; EN 556-1:2024 ; ISO 11737-3:2023 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019-Not applicable ; EN 1422:2014 ; EN ISO 11607-1:2020 ; EN ISO 11607-1:20 A1:23 ; EN ISO 11607-2:2020 ; EN ISO 11607-2:20 A1:2023 ; CEN ISO TS 16775 2021 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; ISO TR 24971:2020 ; EN 17141:2020 ; EN ISO 14644-1:2015 ; EN ISO 14644-2:2015 ; EN ISO 14644-3:2019 ; EN ISO 14644-5:2025 ; ASTM F1980-21 ; ASTM F1886/F1886M-25 ; ASTM F1929-23 ; ASTM F88/F88M-23 ; ISTA Standard 2A ; ISTA Standard 3E ; ISO 2759:2014 ; ISO 3037:2022 ; ISO 8601-1:2019 ; ISO 8601-1:2019 AMD1:2022 ; ISO 2859 1:2026 ; EN ISO 15223-1:2021 ; EN ISO 15223-1:21 AMD2025 ; EN ISO 20417:2026 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ; ISO TR 20416:2020 ;
GMDN:	35246 - Surgical patient preparation kit
EMDN:	V0599 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER

PACKING

Level	Units	Type	Dimension	Stamp	Labels
1 (22 PAP)	1	Flexible peel-open pack	134x185mm		
2 (20 PAP)	30	Carton box	380x255x314mm		labeled
3 (20 PAP)	180	Carton box	786x389x643mm		labeled

Basic UDI	56056221255002L6
	EAN 1th level/nivel:05605622233659
	EAN 2th level/nivel:05605622433653
	EAN Carton Box/Caixa:05605622033655

COMPONENTS		**QUANTITY**	**COMPOSITION**
	Surgical bowl 250ml, blue	MD 1	Colourant, PP pharmaceutical grade.
	Nonwoven ball (with elastic ring), 25x20,5cm, 30grs/sq.m, @60mm "G"	MD 5	Silicone ring, Viscose/Polyester Nonwoven.

	Protection field - wrapping field 40x40cm	MD	1	Cellulose, Polyethylene film.

Important Notes:	The device is intended to be used on a single patient during one single procedure to prevent risks from contamination, including possible infections, and/or functional damage.

Storage instructions:	Store in a dry place at room temperature and protect from sunlight.The product has a good stability and therefore, normal conditions of medical devices storage shall apply
Waste instructions:	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Indications:	For disinfection procedures
Intended purpose:	Intended to provide, in a single pack, the single-use medical device components required for a specific surgical or clinical procedure. Its designation expresses the particular intended purpose (surgical specialty/ clinical procedure)

Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsibility.

Environment - Packaging waste	Weight(gr) of packing material used in 100 pcs	2219	

ISSUED BY: Quality Management Department, 2026/09/17

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