Bastos Viegas
4560-164 Guilhufe, Penafiel - Portugal

Ref: 4396-801

Product Specification

Brand: texart C

DRQ 14/21 REV.00 2020/09/08

Description:	Laparotomy swabs

STERILE EO | isento Latex free | isento PVC free

Final dimensions:	30 cm x45 cm
Composition:	Polyamide,Polyester,Viscose/Polyester Nonwoven.
Construction:	Texart C green
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
CountingEfficiency approx	99 % (see note below)
Colour:	Green
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Sterility Assur. Level_SAL	≤10^-6
Liquid absorbency time	<10 s
Water soluble substances	<0,5 %
Fluorescence	conform
Ether soluble substances	<0,5 %
pH (acidity or alkalinity)	7±1
Tensides (EN 1644-1)	conform
Extract colouring matter	conform
Dry Linting (>0,5µm)	<10 000 Nr. particles
Wet Linting (>0,5µm)	**<4000 Nr. particles**
Weigth/sqm	135±10% g/m^2
Absorption EN 1644-2	Approx. 11 g/g
Absorption EN 13726-1	Approx. 15 g/100cm^2
Dry Tensile strength MD	≥ 110 N/5cm
Dry Tensile strength TD	≥ 100 N/5 cm
Dry Bursting strength	≥ 400 kPa
Wet Bursting strength	≥ 350 kPa
Wet Tensile strength MD	≥ 110 N/5cm
Wet Tensile strength TD	≥ 80 N/5cm
Dry Elongation at breakMD	≤ 50 %
Dry Elongation at breakTD	≤ 70 %
Wet Elongation break MD	≤ 60 %
Wet Elongation break TD	≤ 70 %
Size variation	±3 cm
Note	With X-ray thread

Nr and Revision Date:	40 -- 2022/10/21
CE Class:	IIa
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC
Applicable norms:	EN ISO10993-1:09 AC:10 ; EN ISO 10993-7:08:AC:2009 ; ASTM D4169-22 ; EN ISO 14971:2019 ; EN ISO 11607-1:2020 ; ASTM D4332 01 ; ICH Q1A (2003) ; EN ISO 20417:2021 ; EN ISO 11607-2:2020 ; EN ISO 10993-18:2020 ; EN ISO 10993-1:2020 ; EN ISO 15223-1:2021 ; EN ISO 14971:2019 A11:2021 ; ISO 2759:2014 ; ISO 3037:2013 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019 ; EN ISO 13485:2016 A11:2021 ; CEN ISO TS 16775 2021 ; EN ISO 11737-2:2020 ; EN ISO 10993-7:2008 ; EN 1644-1:1997-Test methods for nonwoven compresses for medical use - Part 1: Nonwovens used in the manufacture of compresses (Chemical specifications criteria adopted from EN 14079 standard) ; EN 1644-2:2000-Test methods for nonwoven compresses for medical use - Part 2: Finished compresses (Chemical specifications criteria adopted from EN 14079 standard) ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN 556-1:2001 AC:2006 ; EN ISO 11737-2:2009 ; EN ISO 10993-18:2009 ; ISO TS 16775:2014 ; ASTM F1980 16 ; ISO 14698-1:2003 ; EN ISO 14971:2012 ; ISO 14644-1:2015 ; ISO 14644-5:2004 ; EN ISO 15223-1:2016 ; EN 1041:2008 A1:2013 ; ISTA Standard 2A ;
GMDN:	39404 - Radiopaque non-woven surgical sponge

Important Notes:	Double packing with units control and traceability stickers

Level		Type	Dimension	Stamp	Labels
1	5	INNER flexible peel-open pack	160x235mm	Quantity control label-TAG	
2	5	DOUBLE Flexible peel-open pack	200x290mm	Double control/traceability labels	
3	100	Folding box	375x285x450mm		labeled
4	200	Carton box	595x395x470mm		labeled

Basic UDI	56056221251012KD
	EAN 1th level/nivel:05605622244020
	EAN 2th level/nivel:05605622444024
	EAN Carton Box/Caixa:05605622044026

Important Notes:	Reinforced with textile net between nonwoven plies, highly absorbent, low linting, functional strength in dry and wet state. Note: Above parameters mean target values. 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.

CountingEfficiency approx	Surgeons and nurses shall never assume that number of surgical sponges, in each pack, is exact at all times. The usual counting efficiency of BV products in double packing with control TAG or tied's is 99 % . The tracking of sponges is full responsibility of the healthcare professionals. In order to avoid retained surgical sponges following surgical operation, (1) follow rigorous manual counting protocols, (2) use sponges marked with a radiopaque marker, as well as, (3) careful examination of the abdomen by the operating surgeon before closure.
Storage instructions	Store in a dry place at room temperature and protect from sunlight. The product has 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.
Intended purpose	For swabbing and absorbing blood and fluids during open surgery. To support organs or tissues during surgical procedures.
	Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsib

Non-harmonized symbols used in article labeling		Check the number of pieces
		Texart C pattern w/x-ray thread

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	1243

ISSUED BY: Quality Management Department, 2023/05/22