Pre-processing Testing Specification on Sugi® Material

Tests/ items	Nominal values
Composition	
Cotton	Approx. 35 %
Regenerated cellulose	Approx. 65 %
Latex	None
Appearance/ Description	
Compressed white-cream absorbent sponge material	
Purity testing	
According to DAB or EP „Verbandswatte aus Baumwolle und Viskose" in the current version.	
Surfactants	Foam must not completely cover the surface after 5 minutes
Water soluble substances	Max. 0.6%
Sulphide	Test solution must be coloured weaker than the reference solution
Drying loss	Max. 8%
Sulphate residue test (sulphate ash)	Max. 0.3%
Fluorescence	Light brown fluorescence and some yellow particles, however must not show strong blue, except for individual fibres.
Foreign fibres	none
Technical properties	
pH value of test solution	6,5 – 7,5
Water absorption	> 1200 %
Area weight range	Approx. 120 – 670g/m²
Bioburden	
Bioburden limit for absorbent materials	< 200 cfu /5 g
Sterilization	
Ethylene oxide	Sterilization by ethylene oxide is recommended for Sugi Products. One-time re-sterilization with ETO does not impair the characteristics of the product.
Gamma rays	One-time re-sterilization with gamma rays will lead to a reduction of the absorptive capacity
Storage / Shelf life	
In sealed climate-secure foils at room temperature. Unsealed storage in a humid environment will lead to an increase of the dry layer thickness (absorption of humidity). Shelf life is 5 years.	

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Biological Tests on Sugi® material

Cytotoxicity (Project 91111501, 1991; 97z021, 1997)

Method:	**ISO 10993-5** Biological evaluation of medical devices, Tests for *in vitro* Cytotoxicity.
Test Material:	SUGI® strips Dimension: 35 x 7.5 x 1.5 mm
Extract Production:	Extraction medium: phosphate buffered physiological saline solution, pH 7.4. Temperature and duration: 37 °C, 24 hours (1991) 37 °C, 72 hours (1997)
Cell Culture:	L 929 mouse fibroblasts
Controls:	Positive: Dilution series Negative: Extraction medium
Test Procedure:	6 parallel cultures per tested dilution of the extracts (100, 60, 30, 10, 3, 1 and 0.3 %). Dyed with crystal violet. Calculation of cell growth inhibition from the extinction values at 580 nm
Results:	Test sample and negative control showed no signs of reactivity (Grade 0) with 30 % concentration of dilution
Conclusion:	SUGI® (non-sterilized and sterilized) does not exhibit pronounced cytotoxicity

Sensitization (Report: 10-05-0923/00-92, 1992)

Method:	**ISO 10993-10** Biological evaluation of medical devices, Tests for irritation and skin sensitization.
Test Material:	SUGI® strips Dimension: 35 x 7.5 x 1.5 mm
Extract Production:	Extraction medium: phosphate buffered 0.9% saline solution, pH 7.4. Temperature and duration: 37 °C, 72 hours
Test Population:	20 guinea pigs
Control Population:	10 guinea pigs
Test Procedure:	Induction exposure to undiluted extract of test material. After Extract production with surface to volume ratio 3 cm^2/ml. Release 14 days afterwards, with this extract
Results:	After 24, 48 and 72 hours no allergic reaction, no toxic effects. Classification numbers for erythema and oedema = 0.
Conclusion:	SUGI® is non-sensitizing

Irritation – Skin (Report: 10-03-0922/01-92, 1992)

Method:	**ISO 10993-10** Biological evaluation of medical devices, Tests for irritation and skin sensitization.
Test Material:	Undiluted extract made of SUGI® strips
Test Population:	3 rabbits
Test procedure:	duration of contact: 4 hours
Results:	After 30 minutes, 1, 24, 48 and 72 hours., no allergic reaction, no toxic effects. Irritation index for animals = 0.
Conclusion:	SUGI® is non-irritating to the skin

Irritation – Ocular (Report: 10-03-0937/00-92, 1992)

Method:	**ISO 10993-10** Biological evaluation of medical devices, Tests for irritation and skin sensitization.
Test Material:	Undiluted extract made of SUGI® strips
Test Population:	3 rabbits
Test Procedure:	duration of contact: 4 hours
Results:	After 1, 24, 48 and 72 hours, no allergic reactions, no toxic effects or eye lesions. Classification number = 0.
Conclusion:	SUGI® is non-irritating to the ocular surface

Update biocompatibility

Cytotoxicity (Project 14Z057, 2014)

Method:	**ISO 10993-5** Biological evaluation of medical devices, Tests for *in vitro* Cytotoxicity.
Test Material:	SUGI® macro swabs (34 mm, non-compressed), SUGI® sponge strips (35 x 7.5 x 1.5 mm, compressed)
Extract Production:	Sterile test items were transferred into the eluent (0.2 per milliliter cell culture medium containing 10 % fetal calf serum) in consideration of absorption capacities: SUGI® macro swabs 14.8 ml/g, SUGI® sponge strips 15 ml/g. Temperature and duration: 37 °C, 24 hours.
Cell Culture:	L 929 mouse fibroblasts
Controls:	Positive: Dilution series of Dimethylsulfoxide Negative: Extraction medium
Test Procedure:	96 parallel cultures per tested dilution of the extracts (100, 30, 10, 3 %). After 4 hours incubation filled with dilution series and incubates for 72 hours at 37 °C again. Dyed with crystal violet. Calculation of cell growth inhibition from the extinction values at 570 nm
Results:	Test samples and negative controls showed no signs of reactivity (Grade 0)
Conclusion:	SUGI® does not exhibit pronounced cytotoxicity

GC/MS Fingerprint (Project 14Y102, 2014)

Method:	**ISO 10993-18** Biological evaluation of medical devices, Chemical characterization of materials.
Test Material:	SUGI® macro swabs (34 mm, non-compressed), SUGI® sponge strips (35 x 7.5 x 1.5 mm, compressed)
Sample Extraction:	Medium: water, isopropyl alcohol, n-hexane. Temperature and duration: 37 °C, 72 hours. In closed glass vials
Controls:	Positive: solution of n-tetradecane dissolved in n-hexane Negative: Pure extraction
Test Procedure:	1 µl of each extract was injected into the GC (duplicate analysis per vial), separated on the capillary column and detected by MS (mass selective detector).
Results & Conclusion:	No semi-volatile organic compounds were detected above the analysis limit