PentaSil
MED-TECH ENGINEERING

SILICONE TUBING FOR MEDICAL USE
SILOPLUS MT - PEROXIDE CURED FORMULAS

Silikonas

Material	*Siloplus® Medical* (Peroxide Cured) Silicone (VMQ Quality – Medical Grade, Non-Recycled) for UltraSafe™ process
Appearance	Transparent
Colour	None
Shape	Circular
Temperature Range	-45°C to +180°C
Properties	Excellent heat stability, transparent, odourless, tasteless, non-toxic, sterilizable (plasma, steam, EtO a.o.), unmeltable, highly elastic, non deformable, top mechanical properties, top safety
Dimensions	From I.D. × O.D = 1,0 × 2,0 mm up to I.D. × O.D = 12,5 × 19,0 mm (over 150 combinations). Other dimensions after request
Uses	Suction (single use), liquid transportation & drainage in all human & veterinary surgical operations. Connection of all types medical equipment & devices
Length/ Package	25 m rolls (or other length on request) in PE transparent bags firmly sealed
Standards/ Certification	EN ISO 9001:2015, EN ISO 13485:2016, CE Mark
Classification	Class I (MDR 2017/745 EU)

Diametras

Available Diameters Inner Ø × Outer Ø in mm	
1 × 2	7 × 13
2 × 4	8 × 11
3 × 5	8 × 12
3 × 6	8 × 13
4 × 7	8 × 14
4 × 8	9 × 12
5 × 8	9 × 13
5 × 9	10 × 14
6 × 9	10 × 15
6 × 10	10 × 18
6 × 12	11 × 16
7 × 10	12,5 × 19
7 × 11	and over 150 combi-nations
7 × 12	

Daug įvairių kombinacijų,
tame tarpe ir 8x10mm bei 7x9mm

Please note that all our Class I silicone tubings for medical use are free of pyrogens, this is why we announce it via our CE declaration and the RoHS & BSE/TSE as well. But, in order to provide a special declaration for biocompatibility tests, we need to proceed specific materials which are accompanied with specificdocuments by our suppliers.

Atkreipkite dėmesį, kad visuose mūsų medicinos reikmėms skirtuose I klasės silikoniniuose vamzdeliuose nėra pirogenų, štai kodėl apie tai pranešame per mūsų CE deklaraciją ir RoHS ir GSE/TSE.Tačiau norint pateikti specialią deklaraciją biologinio suderinamumo bandymams, turime konkrečias medžiagas, prie kurių pridedamos konkrečios mūsų tiekėjų dokumentai.

Ppa. Evan Delibaltas
Dipl. Chem. Ing.
Geschäftsführung

PentaSil
MED-TECH ENGINEERING

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PentaSil Med-Tech Engineering UG

Frankfurt a.M. 18.05.2019

Deklaracija apie biosuderinamumą

Declaration for Biocompatibility Test for Raw Material for Silicone Tube (Elkem Silbione MM 7XXXX)

To Whom It May Concern,

We hereby certify that Pentasil Silicone Tube is manufactured from Elkem Silbione MM 7XXXX USP family of materials, as per attestation attached, which has been evaluated as per Biocompatibility Test According to ISO 10993 and USP VI, Biological Evaluation of Medical Devices and successfully passed all tests.

Below are listed the completed tests and applicable standard parts, as per attachment.

Study Title	ISO 10993 Standard	Which Lab / Lab Report No	Which Lab / Lab Approval Date
Cytotoxicity, MEM Elution			
ISO Guinea Pig Maximization Sensitization			
ISO Intracutaneous Study in Rabbits	Acc. To USP VI	Elkem Bluestar EU Product Stewardship Department / SIL 016-0419	Elkem Bluestar EU Product Stewardship Department / 2016-06-01
ISO Systemic Toxicity	Acc. To USP VI	Elkem Bluestar EU Product Stewardship Department / SIL 016-0419	Elkem Bluestar EU Product Stewardship Department / 2016-06-01
ASTM Hemolysis Study			
USP Rabbit Pyrogen Study	Acc. To USP VI	Elkem Bluestar EU Product Stewardship Department / SIL 016-0419	Elkem Bluestar EU Product Stewardship Department / 2016-06-01

Signed for and on behalf of PentaSil

PentaSil®
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Heidelberg, 29.02.2024

Statement

We, PENTASIL MED-TECH ENGINEERING UG, with address:

Waldhofer Straße 102
DE-69123, Heidelberg, Germany

hereby attestate that our Silicone Tubing for medical use, Type MT Medical, all dimensions, which we supply to:

UAB “Skirgesa”
Address: Energetiku g. 8, LT-52461 Kaunas, Lithuania

are:

- Non-sterile
- Without X-ray contrast strip

Responsible Person

PentaSil Med-Tech Engineering UG
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