

Test protocol ATR-FTIR and mechanical stability analysis prior and after UV sterilization process (qualitative)

Report number: GI 1804-1027 part 02

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Sample: Silicone cover

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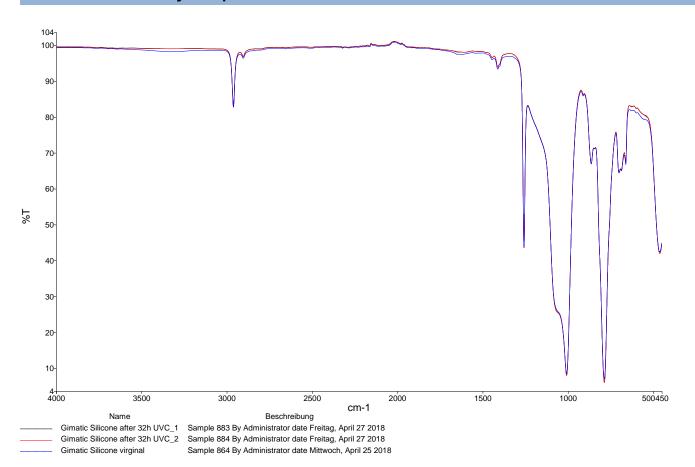
Test sample	
Name:	Silicone cover
Packaging:	Packed in PE-bag
Test samples	10 stripes cut from the silicone cover
	UVC-Exposure for 32 hours

UVC-Exposure for 32 hours using SterilSystems AR 400, 18 W power consumption; distance to lamp 18 cm



FTIR Analysis			
Device / Model:	PerkinElmer Spectrum Two		
Measurement mode:	ATR		
Scan range:	4000 -450 cm ⁻¹		
Number of scans:	4		
Resolution:	4 cm ⁻¹		
Method:	Qualitative Analysis prior and after UVC exposure: Is there any change in chemical bonding visible?		

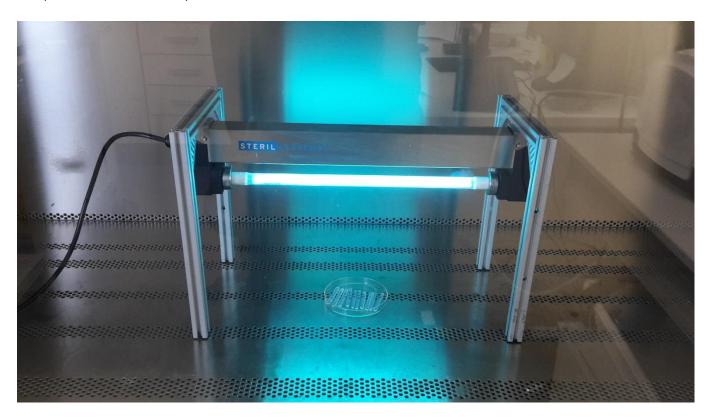
Result ATR-FTIR Analysis: Spectrum

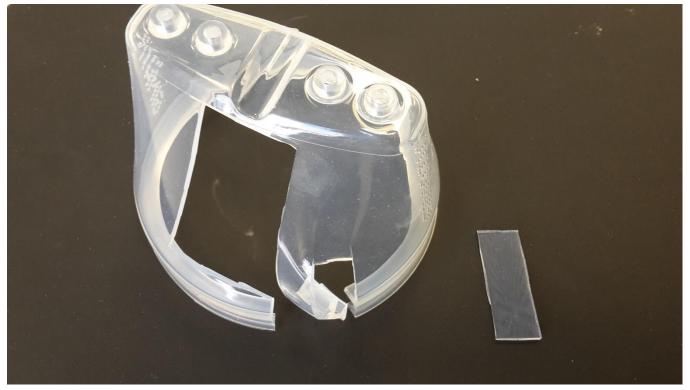


Result: There is no change in IR-Spectra detectable. Therefore, there is no detectable change in chemical structure due to UVC-Exposure



This picutre illustrates the positioning of the material sample in the UVC decontamination device and the place where the samples were cut out of the GIMATIC silicone cover.







Mechanical stability: tensile test	
Test samples:	10 stripes cut from the silicone cover after UVC-Exposure for 32 hours using SterilSystems AR 400, 18 W power consumption; distance to lamp 18 cm
Measurement mode:	Tensile test based in ISO 37
Dimension of test sample:	5 cm x 0.6 mm (tested free material: 3.0 cm (see Type 1 ISO 37)
Number of repetitive tests:	10
Maximum tested elongation	12 cm (Factor 4)
Additional information:	Plastic deformation (length difference prior and after tensile test)

Mechanical stability: tensile test

Sample	stretch factor	initial length	final length	difference
ID		in cm	in cm	in cm
1	> 4	4,9	5,0	0,1
2	> 4	5,0	5,0	0,0
3	> 4	5,0	5,1	0,1
4	> 4	5,0	5,1	0,1
5	> 4	5,0	5,1	0,1
6	> 4	4,9	5,0	0,1
7	> 4	5,0	5,0	0,0
8	> 4	5,0	5,1	0,1
9	> 4	5,0	5,0	0,0
10	> 4	5,0	5,0	0,0
			Average	0,06
			S.D.	0,05

Result:

- The silicone test stripes can be stressed at least to its fourfold length (termination criterion of the test).
- The samples showed, if present, only a slight plastic deformation of approximately 1 %.
- Because the used parameters are all extreme worst case scenarios (distance to strong UVC radiation lamp, fourfold elongation,...) no influence due to UVC sterilization processes to the silicone cover is expected.
- Therefore, UVC-sterilization processes can be safely applied regarding the chemical and mechanical stability of Silicone cover, see also report GI 1804-1027 part 1 for the covered parts of a gripper (no UVC transmittance to the inside of the cover)