

Appendix 3 Declaration from the manufacturer of silicone

Manufacturer/supplier:
Trade name of the silicone material:

D4: Octamethylcyclotetrasiloxane, (CAS NO.556-67-2)

D5: Decamethylcyclopenta-siloxane, (CAS NO.541-02-6)

D6: Dodecamethylcyclohexasiloxane, (CAS NO.540-97-6)

	YES	NO
Is the silicone medical-grade silicone? <i>Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.</i>		
Is the silicone tested according to ISO 10993? <i>Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.</i>		
Is the silicone tested according to USP class VI? <i>Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.</i>		
Do D4, D5 or D6 form part of the silicone material?		
Please state amount of impurities* of D4, D5 and D6 in the silicone material: D4: _____ ppm D5: _____ ppm D6: _____ ppm <i>* Impurities of D4, D5 and D6 are defined as residual products from the raw material production that can be found in the silicone material.</i>		
Is test report showing the amount of D4, D5 and D6 in the silicone material according to test method for silicone elastomer products from CES-Silicones Europe* or any ISO/IEC 17025-validated GC-MS method achieving LOQs at or below 100 ppm attached? <i>* Quantification-of-Residual-Amounts-of-Cyclic-Volatile-Methyl-Siloxanes-in-Silicone-Elastomers_final-002.pdf</i> <i>Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.</i>		
Is documentation for the analysis laboratory fulfils the general requirements of standard EN ISO/IEC 17025 or have official GLP status attached? <i>Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.</i>		

Place and date	Company name
Responsible person	Signature of responsible person
Telephone	Email