Testing sample MySign O

Component of the MySign O which have less or equal then 24h contact to intact skin is the Housing. Components which have indirect contact (air mediated) with mucosal tissue of the respiratory track up to 30 days accordance to the application, are the Flow diverter and the T-adapter.

This material has been evaluated according to the requirements of the ISO 10993 series of standards for Biocompatibility. The following table shows the related test reports and overall results.

Part	Material	Test	Test Report Number/ Certificate	Results
Housing	Lower shell (ABS, TPE)	Cytotoxicity	Certificate from Clariant Masterbatches: - MEVOPUR-WHITE_PE0M176048-ZN - MEVOPUR-WHITE_SB0M176043-ZN	Pass
		Dermal irritation		
		Sensitization		
	Battery cover (ABS, TPE)	Cytotoxicity	Certificate from Clariant Masterbatches: - MEVOPUR-BLUE_PE5M176208-ZN - MEVOPUR-BLUE_SB5M176092-ZN	Pass
		Dermal irritation		
		Sensitization		
Flow diverter	Styrolux 656 C	Cytotoxicity	Report from Medical Device Services GmbH: No. 113388-20-B "Flow-diverter_Cytotoxicity_test.pdf"	Pass
		Chemical analysis	Report from Medical Device Services GmbH: No. 113389-20-B "Flow-diverter_Chemical_analysis.pdf"	
T-adapter	Polyethylene HDPE 25455N	Cytotoxicity	Report from Medical Device Services GmbH: No. 113388-20-A "T-adapter_Cytotoxicity_test.pdf"	Pass
		Chemical analysis	Report from Medical Device Services GmbH: No. 113389-20-A "T-adapter_Chemical_analysis.pdf"	

The results of the tests shows that the Materials of the MySign O are pass the requirements of the ISO 10993 series of standards for Biocompatibility. With this result there are no additional risk for this device.

16.08.19 C.C. Wulle

R&D Engineer

16.08.2019 Tiede

Quality Management