

CONFIRMATION OF MATERIALS

To whom it may concern,

Herewith we confirm products manufactured by SomnoMed are fabricated according to ISO 13485 standards. Materials used in SomnoMed devices have been tested for and met the requirements of ISO 20795 Dentistry – Base Polymers (< 2.0%). The materials used in SomnoMed products have been thoroughly tested for and met biocompatibility standards in accordance with ISO 10993.

Material compositions:

	SomnoDent Fusion Classic	SomnoDent Fusion Flex	SomnoDent Classic	SomnoDent Flex	SomnoDent G2	SomnoDent Herbst Classic	SomnoDent Herbst Flex
Poly(methyl methacrylate)	✓	✓	✓	✓	✓	✓	✓
Polyvinyl chloride	✓	✓	✓	✓	✓	✓	✓
Polyvinyl acetate	✓	✓	✓	✓	✓	✓	✓
SMH BFlex		✓		✓	✓		✓
Polycarbonate	✓	✓			✓		
Stainless Steel grade 1.4301						✓	✓
Stainless Steel grade 1.4303	✓		✓			✓	✓
Stainless Steel grade 1.4404	✓	✓	✓				
Stainless Steel grade 1.4305	✓	✓	✓	✓		✓	✓
Stainless Steel grade 1.4310	✓	✓	✓	✓		✓	✓
Silver Solder						✓	✓

Please note including of following variants:

	Nickel Free*	Hooks for elastics
Stainless Steel grade 1.4456	✓	
Titanium	✓	
Stainless Steel grade 1.4303		✓

*<0.2% Nickel

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SomnoMed

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