

Product Information
On

Quadrant Flow
Light curing Flowable Composite

Legal manufacturer:	Cavex Holland BV Fustweg 5 2031CJ Haarlem The Netherlands SRN: NL-MF-000000423
Regulatory evaluator: Signature:	Danny Stoelinga 
Regulatory manager: Signature:	Richard Woortman 
Version:	2023-02

Table of Contents:

1. Introduction.....	3
2. Composition.....	4
3. Manufacturing.....	4
4. Laboratory control.....	4
5. Shelf-life test.....	5
6. Quality Control.....	5
7. Statement of non-toxicity.....	5

1. Introduction

Quadrant Flow is a flowable light curing radiopaque composite filling material, designed as an addition to the existing Quadrant composites. Quadrant Flow has ideal flow properties, which assures perfect coverage of the tooth structure. Quadrant Flow is based on Bis-GMA monomer and contains like all other Quadrant composites Barium-glass and SiO₂ fillers. The unique properties of barium glass are its strong “chameleon effect”, gloss and strength. Quadrant Flow is excellently compatible with other composites in the Quadrant range (Anterior Shine and Universal LC).

Quadrant Flow is available in 4 shades:

- Quadrant Flow A2, A3, A3.5, OA2

Quadrant Flow is the “all-purpose” material, which can be used for a wide range of indications such as:

- minimally invasive fillings
- base under composite restorations
- cavity lining
- restorations to composite
- splints
- retention of threads and brackets
- fissure sealing

Quadrant Flow is available in syringe of 1,8 g (1 ml) and can be easy applied using single-use bendable metal needle tips. Quadrant flow requires the application of an adhesive bonding system such as Quadrant UniBond or Quadrant Uni-1-Bond in the so-called “total etch technique”, in combination with an etching agent such as Quadrant Total Etch.

Quadrant Flow is developed and manufactured by Cavex Holland B.V., a Company that is certified according to the provisions of the Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and ISO13485.

Quadrant Flow bears the CE-Mark of conformity.

2. Composition

The basic ingredients of Quadrant Flow are:

Raw material	% Mass
Methacrylate-based monomers	39
Silica, silicate glass and fluoride containing fillers	> 60
Polymerisation catalysts	< 1
Inorganic pigments	< 1

3. Manufacturing

Basically, the monomers and fillers are carefully weighed and blended in high-performance kneading equipment under vacuum, in order to obtain a composite paste, free of air bubbles. The last production step is to add the inorganic pigments in order to obtain the various shades in which the product is made available. Finally, the composite paste is filled into syringes.

4. Laboratory control

Quadrant Flow is in full compliance with the EN ISO 4049 standard for resin-based dental filling materials. The following table gives typical values for the most important properties:

Characteristic	ISO 4049	Quadrant Total Flow	Unit
Appearance	Coloured, homogeneous paste flowable	Coloured, homogeneous paste flowable	
Biocompatibility	Must comply	Must comply	
Sensitivity to ambient light	60 + 5 s unpolymerized	60 + 5 s unpolymerized	
Depth of cure	1 - 10	1 - 10	mm
Flexural strength	50 - 250	50 - 250	Mpa
Water sorption	0 – 40	0 – 40	$\mu\text{m}/\text{mm}^3$
Water solubility	0 – 7,5	0 – 7,5	$\mu\text{m}/\text{mm}^3$
Colour	According shade guide	According shade guide	
Colour stability	Must comply	Must comply	
Radio opacity – X-ray	More than 1 mm aluminium	More than 1 mm aluminium	
Packaging and marking	Must comply		

5. Shelf-life test

Based on the results of these tests, we can guarantee the good qualities of Quadrant Flow for a period of 36 month, provided the product is stored below 25 °C/77 °F when not in use.

6. Quality Control

A batch of Quadrant Flow, that has passed all the tests, is released for sales. In case of one or more requirements being not in specification, that batch is withdrawn and not sold.

7. Statement of non-toxicity

We hereby declare that Quadrant Flow can be safely used and is non-toxic to the patient as well as to the dental team.

Quadrant Flow will also normally not be irritant to oral tissues and it does not contain any hazardous ingredients in sufficient concentration to be harmful to human beings, when used as directed.