Product Information On Quadrant Uni-1 Bond (Light curing Adhesive)				
Regulatory evaluator:	Danny Stoelinga			
Signature:				
Regulatory manager:	Richard Woortman			
Signature:	Blackerter			
Version:	2022-12			

YOUR IMPRESSION IS OUR SPECIALTY



Table of Contents:

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

Page **2** of **4** Revision: 0

YOUR IMPRESSION IS OUR SPECIALTY

CAVEX

1. Introduction

Quadrant Uni-1-Bond is a light curing, single component bonding agent for universal use in combination with adhesive restorations. Quadrant Uni-1-Bond primes and bonds in one step. Quadrant Uni-1-Bond is an ethanol-based formulation of light-activated, adhesive resins.

Quadrant Uni-1 Bond is developed and manufactured by Cavex Holland B.V. of Haarlem, The Netherlands, a Company that is certified according to the provisions of the Regulation (EU) 2017/745 concerning Medical Devices, against ISO 9001 and ISO 13485.

Quadrant Uni-1 Bond bears the CE marking of conformity.

2. <u>Composition</u>

The following materials are used in Quadrant Uni-1 Bond:

Function	Raw Material	% Mass
Monomer	Urethandimethacrylate	28.5
Monomer	Hydroxyethylmethacrylate	16.0
Monomer	4-Methacryloxyethyltrimellitanhydrid (4-META)	4.0
Active	Glutaraldehyde	2.5
Monomer	Carboxylic acid based monomer	7.0
Catalyst	Camphoroquinone catalyst system	0.5
Solvent	Ethanol	30.0
Viscosity	Distilled water	11.5

3. Manufacturing

The manufacturing of Quadrant Uni-1 Bond is the result of gradually mixing all raw materials into a homogeneous, clear yellow liquid. Quality controls ensure the good quality of Quadrant Uni-1 Bond after the manufacturing process.

YOUR IMPRESSION IS OUR SPECIALTY



4. <u>Laboratory control</u>

Of every single batch of Quadrant Total Etch the Appearance, Refractive index and Shear bond strength is tested according to an in-house test method. At present, a product standard for light curing adhesives is not available. Therefore, quality control is carried out according to a number of in-house standards.

The following tests are performed to ensure the good quality of the raw materials on the product Quadrant Uni-1 Bond:

Characteristic	Internal specifications	Quadrant Uni-1 Bond	
Appearance	homogeneous	homogeneous	
Refractive index	1,4255 – 1,4295	1,4275 – 1,4295	
Shear bond strength	>20	>20	Мра

5. <u>Shelf-life test</u>

Quadrant Uni-1-Bond should be used at room temperature. Based upon the 2004,2012 and 2020 evaluation we can guarantee the good quality of Quadrant Uni-1-Bond for a period of 36 month when stored at temperature -10 to 25°C. However, we recommend that the product is stored in a refrigerator when not in use.

6. **Quality Control**

A batch of Quadrant Uni-1 bond, 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. <u>Statement of non-toxicity</u>

We hereby declare, that Quadrant Uni-1 bond can be safely used and is non-toxic to the patient as well as to the dental team.

Page 4 of 4 Revision: 0

YOUR IMPRESSION IS OUR SPECIALTY

CAVEX