

DECLARATION OF CONFORMITY

We

**Cavex Holland B.V.
POBox 852, 2003 RW Haarlem**

declare under our own responsibility that the products

**Cavex RushBrush
ADULT PRE-PASTED TOOTHBRUSH**

to which this declaration concerns, is in compliance with the following standard(s) or other normative document(s)

Internal product specifications (see Annex)

Cavex Holland B.V. is a company that is certified according to the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC concerning Medical Devices.

Conformity assessment performed by:

**TÜV Rheinland Product Safety GmbH
Am Grauen Stein
D-51105 Köln, Germany**

Haarlem, 01 August 2010



**Richard Woortman
Manager Technical Services**



CAVEX RUSH BRUSH

- | | | | |
|-------|-----------------------------------|---|---|
| 1. | Description | : | ADULT PRE-PASTED TOOTHBRUSH |
| 2. | Supplier's ref | : | Cavex RushBrush |
| 3. | Body | | |
| 3.1. | - Material | : | GPPS - 525 |
| 3.2. | - Colour | : | RED(032C),YELLOW(101C), BLUE(2728C) & GREEN(354C) |
| 3.3. | - Length | : | 155 ± 1.0mm |
| 3.4. | - Width (Head) | : | 12mm |
| 4. | Tuft Hole | | |
| 4.1. | - No. of Tuft Holes | : | 28 |
| 4.2. | - Depth of Tuft Hole | : | 3.2±0.2 mm |
| 4.3. | - Diameter of Tuft Hole | : | 1.6±0.05 mm |
| 5. | Printing (logo) | | |
| 5.1. | - Description (logo) | : | Cavex RushBrush |
| 6. | Filament | | |
| 6.1. | - Material | : | Nylon 610 |
| 6.2. | - Type (Rounding) | : | Excellent |
| 6.3. | - Diameter | : | 0.18mm |
| 6.4. | -Length (at highest point) | : | 10±0.5mm |
| 6.5. | - Stiffness | : | Soft |
| 6.6. | -No. of Filaments / Tuft | : | 20±2 |
| 6.7. | - Colour | : | Nature(NC 001) and Colored match with handle's colouring |
| 7. | Staple | | |
| 7.1. | - Material | : | Aluminum wire |
| 7.2. | - Dimensions | : | Length : 2.00+0.15mm |
| | Width | : | 1.30±0.10 mm |
| | Thickness | : | 0.25±0.05 mm |
| 8. | Pasted Solution | | |
| 8.1. | -Ingredients | : | Glycerin, Deionized Water, Sodium Lauryl Sulfate, Sodium Carboxymethyl Cellulose, Mentholum Flavor, Sodium Benzoate, Sodium Saccharin |
| 8.2. | -Colour | : | Transparent |
| 9. | Packaging | | |
| 9.1. | -Inner Box Material | : | Duplex Board with White Back |
| 9.2. | -Inner Box Dimensions | : | 16cm(L) x 16cm(W) x 11cm(H) |
| 9.3. | -Outer Carton Material | : | Corrugated Cardboard |
| 9.4. | - Outer Carton Dimensions | : | 57cm(L) x 33.5cm(W) x 18cm(H) |
| 10. | Packing configuration | | |
| 10.1. | - No. Per polybag | : | 1 |
| 10.2. | - Units per Box | : | 100(25pcs of each colour) |
| 10.3. | - Units per Outer Carton | : | 1000 |