

ComfortBrace Strips Technical File

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Company:

Comfort Brace LLC
1971 NE 31 Street
Lighthouse Point, FL 33064

File Data Contact:

Bill DiEdwardo
Owner/Operating Manager

Product:

ComfortBrace Strips
ComfortBrace Dental Brace Protective Strips

Designation:

Class 1 Medical Device

Description:

A dental brace protective strip that will protect the inner lips, tongue and gums from abrasive dental braces. A protective strip that can be peeled of a backing and easily be applied to teeth and braces. A protective strip that can be worn while eating, drinking and sleeping. A protective strip that will save time when taking dental impressions.

Ingredients:

Polyvinylpyrrolidone (PVP)
Acrylates Copolymer
Sorbitol
Water
Hydroxyethyl cellulose (HEC)
Carbomer 980
Mint
Polyethylene: Textured strip
Polypropylene: Backing

Strip Dimensions:

15mm X 80mm

Versions:

24-strip retail box
6-strip box

User Manual:

See *Directions front and back* file

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CE Directives:

See *Dec of Conf2* file

See *Dec of Con Auth-Rep* file

Hazard analysis:

See *ComfortBrace MSDS Ingredients* file

Quality control tests, methods and acceptance criteria:

See *ComfortBrace Strips Quality Control Spec* file

Photograph- Brochures

See *Show Sell Sheet orth2Swe* file

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