

ComfortBrace

Dental Brace Protective Strips

Approved by the Medical Devices Bureau, Health Canada

Based on the product and information provided, the ComfortBrace is a Class I medical device by Rule 2(2).

Rule 2:

(1) Subject to subrules (2) to (4), all invasive devices that penetrate the body through a body orifice or that come into contact with the surface of the eye are classified as Class II.

(2) A device described in subrule (1) that is intended to be placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum is classified as Class I.

As we discussed by phone, a medical device establishment licence is required. However, if you are selling solely through distributors who hold establishment licences themselves, you are exempt from holding one as per section 44(2)(d) of the Medical Devices Regulations

<http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/index.html>

If you have further questions about the establishment licence, please contact the Establishment Licensing Unit at MDEL_questions_LEPIM@hc-sc.gc.ca.