DENTALBIZ GROUP

Rodwell Orthodontic Laboratory Pty Ltd
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www.dentalbiz.com.au

Device Information

INFORMATION FOR USE (IFU)

This oral device has been constructed according to the instructions provided by an appropriately qualified and registered dental practitioner.

Patients MUST follow the instructions for use and maintenance that is provided by their practitioner.

For further technical information relating to the materials and components used in the construction of this device, please use the QR link below.

www.dentalbiz.com.au/device_info.html

THERAPEUTIC GOODS (MEDICAL DEVICE) REGULATION

This patient-matched / custom-made device is routinely constructed using articles that have been included within the Australian Register of Therapeutic Goods (ARTG).

Where an exemption is not provided in the medical device regulation, our organisation has made transitional arrangements for any ARTG inclusion that may be required by the Therapeutic Goods Administration (TGA).

DECLARATION OF CONFORMITY

Our laboratory principle confirms that the device complies with the “essential principles” and is constructed according to manufacturer instructions and intended purpose.

QUALITY MANAGEMENT CERTIFICATION

Our laboratory is certified by the Australian Dental Technicians Association (ADTA). Dental laboratory certification provides guidelines for conformity and quality assurance for device, workplace, health and safety management.