



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	121284	Henry Schein Halas - Orthodontic appliance, wire
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ARTG entry for	Medical Device Included Class IIa
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Sponsor	Henry Schein Halas
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Postal Address	Locked Bag 5003, ALEXANDRIA, NSW, 2015 Australia
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ARTG Start Date	12/08/2005
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Product Category	Medical Device Class IIa
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Status	Active
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Approval Area	Medical Devices
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Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.

- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Scheu-Dental GmbH	Am Burgberg 20 Iserlohn, , 58642 Germany

Products

1 . Orthodontic appliance, wire

Product Type	Single Device Product	Effective Date	12/08/2005
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GMDN	16204 Orthodontic appliance, wire
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Intended Purpose	This dental device which is used as a component of an orthodontic appliance system is basically used to exert pressure on teeth in order to alter their position. This wire is of varied dimensions and grades.
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Specific Conditions

No Specific Conditions included on Record

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