

Department of Health and Aged Care

Application to Vary a Listing on the Stoma Appliance Scheme

About this form

This form should be used by sponsors of stoma-related products seeking to make an administrative variation to a listing on the Stoma Appliance Scheme (SAS) Schedule.

If the variation sought will affect a product's classification, pricing, maximum quantity, or composition, or to add an additional product to an existing product range, sponsors should use the appropriate 'Application to List a Product' form.

This form must be completed with reference to the *Application and Assessment Guidelines* (Guidelines). The Guidelines are available on the SAS webpage under 'Resources' or at <u>https://www.health.gov.au/resources/publications/stoma-appliance-scheme-application-and-assessment-guidelines</u>.

A separate form must be used for products to be varied under each SAS code.

Variations are generally processed by the Stoma Product Assessment Panel (SPAP) Secretariat.

It is the responsibility of the sponsor to provide sufficient information relevant to each of the sections for full assessment of their application.

Please ensure all sections of the application are complete before submitting your application to the Department of Health and Aged Care (the Department). A checklist has been provided for your assistance.

Completed applications and supporting material should be sent to the Department using the contact details listed below:

Contact Details for the SPAP Secretariat:

Address: Stoma Appliance Scheme GPO Box 9848 CANBERRA ACT 2601 Phone: (02) 6289 2308 Email: <u>stoma@health.gov.au</u> Web: <u>www.health.gov.au/stoma</u>



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Section 1 – Applicant Details

The applicant must be the sponsor of the stoma-related product in Australia.

Application Details of Sponsor		
Company		
ABN		
Address		
City		
State		
Postcode		
Contact Name		
Position		
Phone		
Email		

Applicant Declaration

I declare that the information provided on this form and any attachments is true and correct to the best of my knowledge.

I accept that this application and/or its contents will be made available to the Stoma Product Assessment Panel which will consider it for the purpose of making recommendations to the Department of Health and Aged Care.

Applicant Signature	
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Date



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Section 2 – Product Information to be varied

The purpose of this section is to establish the product/s for which a variation is being sought.

Please use a separate 'Application to Vary a Listing' for each individual SAS code.

In the box below, provide the current product details for the product as it is currently listed on the schedule. Any variation to this information can be provided in Section 3, 'type of variation', on the next page.

Product name	
SAS Code	
Product Code(s)	
Group	
Subgroup	



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Section 3 – Type of variation

The purpose of this section is to establish the nature of the variation which is being sought. Only complete the relevant table for the type of variation that applies to this application

Variation to company code

Existing company code	
New company code	

Variation to sponsor name

Existing sponsor	
name	
New sponsor name	

Variation to product description

New product	
description	
(in full)	

Variation to product name

Existing product name	
New product name	

Variation to pack size

Existing pack size	
New pack size	



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Section 4 – Additional Information

The purpose of this section is to allow any further information to be provided which may be relevant to the application and has not been included in previous sections. Any confidential information in the application should also be identified here.

Section 5 – Supporting Documentation

All attachments relating to this application should be correctly labelled and indicate the relevant section in the application they refer to in the table below (attach a separate page/s if additional space is required)

File title	Relevant Section in Application	

Application Checklist

Information	Included
Section 1 – Application details and declaration	
Section 2 – Product information	
Section 3 – Type of variation	
Section 4 – Additional information including confidential information	
Section 5 – Supporting documentation & checklist	