

This document is only to be used as an aid for translating and understanding the Swedish application form. This document cannot be used as an application form.



Appendix A

APPLICATION
for including a medical device
in the reimbursement system

Type of medical device

- Administration of pharmaceuticals to the body Stoma Medical self-monitoring

Company name, VAT number and address

[Redacted]

Name, telephone, fax and E-mail for primary contact(s)

[Redacted]

Medical devices

	Product name	Package text (limited to 70 characters)	Number of items/package	Requested AIP
1.	[Redacted]	[Redacted]	[Redacted]	[Redacted]
2.	[Redacted]	[Redacted]	[Redacted]	[Redacted]
3.	[Redacted]	[Redacted]	[Redacted]	[Redacted]
4.	[Redacted]	[Redacted]	[Redacted]	[Redacted]
5.	[Redacted]	[Redacted]	[Redacted]	[Redacted]

Patient category

[Redacted]

Estimated number of patients

[Redacted]

Average cost per day

(include supporting data for calculations)

1.	[Redacted]
2.	[Redacted]
3.	[Redacted]
4.	[Redacted]
5.	[Redacted]

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Calculated turn-over at full scale sales (AIP)

1.	[REDACTED]
2.	[REDACTED]
3.	[REDACTED]
4.	[REDACTED]
5.	[REDACTED]

Comparable medical devices or treatments (include supporting data)

For each applied medical device stated above, specify the comparison under each item below.

Item number	Product name, package details, number of items	AIP
1.	[REDACTED]	[REDACTED]
2.	[REDACTED]	[REDACTED]
3.	[REDACTED]	[REDACTED]
4.	[REDACTED]	[REDACTED]
5.	[REDACTED]	[REDACTED]

Applying company hereby certifies that the products are properly CE-marked.

Applying company hereby consents to this application and all enclosed supplements being presented to the Pharmaceutical Benefits Group for County Councils during deliberation with TLV according to article 9 of the Act (2002:160) on Pharmaceutical Benefits, etc. The Pharmaceutical Benefits Group for County Councils confirms that none of the data will be forwarded to a third party, or be used for any other purpose than deliberation with TLV.

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Appendices:

- Health economic analysis
- Data for average cost per day
- Supporting data for comparable products, etc.
- Swedish user-manual

Other documents:

All data for the application must be entered to be regarded as complete.

Signature

Date

Signature

- Document confirming that the signatory is an authorized representative is available at TLV.
- Document confirming that the signatory is an authorized representative is enclosed.

Send application to:

Tandvårds- och läkemedelsförmånsverket
Box 225 20
SE 104 22 Stockholm
Sweden