

**Swan labelling of**

**Peritoneal dialysis (PD) and intravenous (IV) sets**

**Draft for review 14 March 2007**



**Nordic Ecolabelling**

In November 1989, the Nordic Council of Ministers adopted a measure to implement an official voluntary ecolabelling scheme, the Swan. The organizations/companies listed below administer the Swan ecolabelling schemes on assignment from their national governments.

For further information, please visit the respective Web sites:

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This document may be copied only in its entirety and without any type of change.

Quotations may be made provided that Nordic Ecolabelling is stated as the source.

# Swan labelling of Peritoneal dialysis and intravenous sets

098, Draft for review 14 March 2007

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## **What are Swan-labelled PD and IV sets?**

The Nordic health care sector uses PVC plasticised with phthalates, such as DEHP, in many disposable products. The incineration of PVC in waste incineration facilities generates large amounts of toxic residues. These residues need to be disposed of in controlled landfills. Many phthalates are problematic to health. DEHP reduces the size of testicles in laboratory animals and is classified as reproductive toxic and teratogenic.

For health care products such as peritoneal dialysis (PD) and intravenous (IV) sets there are safe and economically viable alternatives. EU legislation in the area is extensive and imposes strict requirements as to the safety of the products. Swan-labelled peritoneal dialysis and IV sets do not contain PVC or harmful plasticisers. The alternative plastic generates much less toxic residue upon waste incineration and does not require the same quantity of plasticisers.

In peritoneal dialysis sets alone, Nordic Ecolabelling estimates that between 175-350 tons of phthalates can be avoided on a yearly basis if the alternatives are used.

## **Why choose the Swan label?**

- Manufacturers and distributors may use the Swan trademark for marketing. The Swan label is a very well-known and well-reputed trademark in the Nordic region.
- The Swan label is a cost-effective and simple way of communicating environmental work and commitment to customers and suppliers.
- Environmentally suitable operations prepare the products for future environmental legislation.
- Environmental issues are complex. It can take a long time and extensive resources to gain an understanding of a specific area. Swan labelling can be seen as an aid in this work.
- The Swan label not only covers environmental issues but also quality requirements, since the environment and quality often go hand in hand. This means that a Swan licence can also be seen as a mark of quality.

## What can carry the Swan label?

Sets, or parts of sets, intended and marketed for use in intravenous (IV) or peritoneal dialysis (PD) treatment according to the EU directive on Medicinal Products, 2001/83/EC and or the directive on Medical Devices 93/42/EEC with subsequent amendments and adaptations qualify for a Swan label if they are not encompassed by other Nordic Ecolabelling criteria at the time of application.

Other disposable health care products may be included in the product group if these are encompassed by the aforementioned directives. In case of interest, please contact Nordic Ecolabelling. See page two for contact information.

## How to apply

Each requirement is marked with the letter R and a number. R stands for “requirement”. All requirements must be fulfilled to be awarded a licence. Other requirements, which are intended to ensure that the ecolabelling requirements are observed after the licence has been granted, are labelled M plus a number and must also be fulfilled.

### Application



Applications can most easily be submitted by using the criteria document as a check list. A number of standard forms are attached to the criteria document as appendices to facilitate the documentation of the requirements.

The entire application comprises a completed application form, a completed check list, i.e. the criteria document, and associated documentation. Applications should be submitted to Nordic Ecolabelling in the country in which the applicant carries on activities (see addresses on page two). Manufacturers from outside the Nordic countries wishing to apply must make arrangements to do so with the secretariat in one of the Nordic countries.

The last section of the document contains a list of definitions and explanations that are central to the proper interpretation and understanding of the requirements. In case of dispute, the definitions and explanations in the list should be taken as authoritative.

### Icons in the text

The text describes how the applicant shall demonstrate fulfilment of each requirement. There are also icons in the text to make this clearer. These icons are:

-  Enclose documentation
-  The requirement is checked on site

### **On-site inspection**

In connection with handling of the application, Nordic Ecolabelling normally performs an on-site inspection to ensure adherence to the requirements. For such an inspection, data used for calculations, original copies of submitted certificates, test records, purchase statistics, and similar documents that support the application must be available for examination.

An inspection visit might typically involve checks on the following:

- the manufacturer's procedures and instructions for ensuring compliance with the ecolabelling requirements (M2)

### **Costs**

An application fee is charged to companies applying for a licence. There is an additional annual fee based on the turnover of the Swan-labelled product.

### **Enquiries**

Please contact Nordic Ecolabelling if you have any queries or require further information. See page two for addresses.

## 1 General requirements

### R1 Description of the product

Describe the product.

- Appendix 1 duly completed and signed by the applicant.

## 2 Environmental and health requirements

### Plastic material

#### R2 Chlorinated plastics in the product and packaging

Chlorinated plastics such as PVC are not allowed in the product or in the packaging.

- Appendix 2 duly completed and signed by the manufacturer of the product.

### Plasticisers, other additives and adhesives

The plasticisers and other additives added to the plastic and adhesives used in or on the different parts in the product must fulfil requirements R3 and R4.

#### R3 Endocrine disruption

No plasticisers or other additives must be regarded as having potential for endocrine disruption in accordance with official lists published in any Nordic country or the EU.

*(See [http://europa.eu.int/comm/environment/docum/01262\\_en.htm](http://europa.eu.int/comm/environment/docum/01262_en.htm))*

*Note that the EU list of substances causing endocrine disruption has a class 3C, in which the assessment is: "No scientific basis for inclusion in list. Data available indicating no scientific basis for inclusion in list." These substances are not regarded as causing endocrine disruption.*

- Appendix 3 duly completed and signed by the producer of the plastic raw material and Appendix 4 duly completed and signed by the suppliers or producers of plasticisers and other additives.

#### **R4 Hazardous to health and the environment**

No plasticisers, other additives or adhesives must be classified in any of the following hazard categories (with applicable risk phrases in parenthesis):

- carcinogenic with T (R45, R49)
- carcinogenic with Xn (R40)
- reproductive toxic with T (R60, R61)
- reproductive toxic with Xn (R62, R63)
- causing heritable genetic damage with T (R46)
- causing heritable genetic damage with Xn (R68)
- very toxic with T+ (R26, R27, R28 R39)
- toxic with T (R23, R24, R25, R39, R48)
- harmful with Xn (R40, R48)
- allergenic with Xn (R42)
- allergenic with Xi (R43)
- environmentally hazardous with N (R50, R50/53, R51/53, R59)
- environmentally hazardous without N (R52/53, R52, R53)

The classification is in accordance with current rules in Denmark, Finland, Iceland, Norway and Sweden. These rules are based on EU Directive 1999/45/EC with subsequent amendments and revisions.

☒ See R3.

### **The product**

#### **R5 Labelling of plastic parts and packaging**

All plastic parts in the product as well as packaging must be labelled in accordance with DIN 6120 Part 2, ISO 11469 or an equivalent labelling scheme. However, plastic labels are exempted from this requirement.

☒ See R2.

#### **R6 Recycling system**

The relevant national regulations, laws and/or industry-wide agreements on recycling systems for products and packaging must be fulfilled in the Nordic countries in which the Swan-labelled products are marketed.

☒ See R1.

#### **R7 SCENIHR Recommendations**

Recommendations from the EU scientific committee on emerging and newly identified health risks, SCENIHR, must always be followed unless they contradict requirements in the criteria document.

*SCENIHR's Opinions can be found on*  
[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/04\\_scenihhr\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/04_scenihhr_en.htm)

☒ Appendix 1 and 2 duly completed and signed.

### 3 Quality and safety requirements

#### R8 Safety

The product must be safe to use and function well.

- A copy of the approval from an authorised authority for marketing the product according to applicable legislation. The approval must cover all the countries in which the product is sold.

### 4 Other requirements

To ensure that the Swan requirements are met, the following procedures must be implemented.

The environmental management requirements are fulfilled by completing and following the instructions in Appendix 5 or having added equivalent sections to the internal procedures of the organisation. If the applicant wishes to adjust the procedures (without changing the contents) in Appendix 5 in order to secure a better fit to management systems already established in the company, they may be ordered electronically from Nordic Ecolabelling in an editable format.

#### M1 Legislation and regulatory requirements

The applicant must ensure compliance with the applicable legislation, including regulations governing safety, the working environment, the external environment and any permits required by the authorities for the production and handling of the ecolabelled product.

- Signed application form.

#### M2 Organisation and responsibility

The applicant must have procedures and an organisational structure that ensures that the requirements of the ecolabelling criteria are fulfilled at all times. A person responsible for monitoring or quality and a contact for ecolabelling must be appointed.

- Completed and signed Appendix 5. If environmental or quality management has been certified (ISO 9000/14000 or EMAS) and if procedures equivalent to those in Appendix 4 form part of the certified system, copies of the relevant procedures are sufficient.

#### M3 Documentation of the application

The applicant must ensure that all documentation relating to the application and ongoing supervision of the requirements is collected in one place.

- See M2.

**M4 Recording of journal**

The manufacturer must have a system in place for recording documentation showing compliance with the ecolabelling requirements in a journal.

If the manufacturer has a certified environmental management system (ISO or EMAS) covering the production of the eco-labelled product, information from an environmental audit or an environmental report from this can be used as a journal. This applies if the method of specifying data is the same as in this document.

The same applies if the business operates green accounts, environmental reports or the like.

See M2.

**M5 Traceability**

Swan labelled products must be possible to trace in the manufacturing process so that they are distinguished from other non labelled products.

See M2.

**M6 Marketing**

The Swan label must be marketed and used in accordance with the section on the design of the ecolabel and “Rules for Nordic ecolabelling” of 12 December 2001 or later versions.

Completed and signed Appendix 6.

## Design of the Swan label

The ecolabel and the allotted licence number together with the explanatory text and the additional text (indicated in the figure as XY) must have the following design:



licence number

XY

Explanatory text

The licence number and the additional text may also follow the underside of the logo or be printed elsewhere in connection with the logo. The surtext may also be omitted or written elsewhere in connection with the logo. The surtext varies from country to country. See “Rules on Nordic ecolabelling” of 12 December 2001 or later versions for the correct surtexts in various languages and for selection of colour.

The explanatory text may be written elsewhere in connection with the logo. The text must be one or more of the following in case the ecolabelled product contains liquid pharmaceuticals:

Danish: Svanens krav dækker ikke indholdet  
Swedish: Svanens krav omfattar inte innehållet  
Finnish: Joutsenmerkkivaatimukset eivät koske tuotteen sisältöä  
Norwegian: XXX  
Icelandic: XXX  
English: The Swan requirements do not cover the content

The size of the ecolabel, additional text, explanatory text and licence number must be such that they are clear and legible.

### **Swan-labelled peritoneal dialysis and intravenous sets**

Licensed products can use the Swan-labelled and they can be marketed with the Swan label. The eco-label must appear on the product or on the packaging of the product. For peritoneal dialysis (PD) sets the additional text (shown in the figure as XY) must be one or more of the following:

Danish: Peritoneal dialyse set  
Swedish: Peritoneal dialys set  
Finnish: Dialyysitarvikkeet  
Norwegian: Peritoneal dialyse sett  
Icelandic: XXX  
English: Peritoneal dialysis set

For IV sets, the additional text (shown in the figure as XY) must be one or more of the following:

Danish: Infusions set  
Swedish: Infusions set  
Finnish: Infuusiotarvikkeet  
Norwegian: Intravenøs (IV)-sett  
Icelandic: XXX  
English: Intravenous set

If the licence holder wishes to use a designation other than above mentioned as additional text or a language other than those specified, advance approval must be secured from Nordic Ecolabelling.

If only a part of the PD or IV set is ecolabelled an alternative additional text must be used. The alternative additional text must clearly indicate the designation of the part (e.g. Tube for IV set) and must be approved by Nordic Ecolabel in advance.

## Follow-up inspections

Nordic Ecolabelling may decide to check whether the ecolabelled product fulfils the Swan requirements during the licence period. This may involve a site visit or random sampling.

The licence may be revoked if it is evident that the eco-labelled product does not meet the requirements.

In the case of peritoneal dialysis and intravenous sets, the inspection might typically involve the following:

- check that the distribution of responsibilities is updated (M2)
- check with the supervisory authorities that the manufacturer of peritoneal dialysis and intravenous sets has nothing outstanding in relation to compliance with the applicable legislation
- check that materials included in Swan-labelled peritoneal dialysis and intravenous set do not consist of PVC.

## How long is a licence valid?

Nordic Ecolabelling adopted the criteria for peritoneal dialysis and intravenous sets on XXX. The criteria are valid until XXX.

The ecolabel licence is valid providing the criteria are fulfilled and until the criteria expire. The validity period of the criteria may be extended or adjusted, in which case the licence is automatically extended and the licensee informed.

Revised criteria shall be published at least one year prior to the expiry of the present criteria. The licensee is then offered the opportunity to renew their licence.

## Future criteria

In future criteria Nordic Ecolabelling will among other things consider whether to:

- Include requirements as to energy
- Include requirements as to recyclability of materials
- Include requirements as to process contaminants and residues

## Terms and definitions

<b>Term</b>	<b>Explanation or definition</b>
Additive	A chemical substance or preparation added with intention to the plastic. Additives can be heat stabilizers, antioxidants, UV-stabilizers, flame retardants, dyes, pigments, plasticisers, etc.
Adhesives	Adhesives in their pure form but also adhesives supplied on prefabricated labels and so on.
Chemicals	Chemical preparations or chemical substances. The authorities have rules for classifying chemical preparations and substances.
IV (intravenous treatment)	Infusion of medications, nourishment (such as total parenteral nutrition), and other fluids, such as dextrose or electrolyte solutions to the patient. An IV set-up includes a bag containing a solution and tubing that conveys the solution from the bag to the catheter inserted into the vein.
Manufacturer	Company that manufactures the product that is going to be labelled with the Swan. Manufacturing comprise the plastic processing such as injection moulding, extrusion, thermoforming, blow moulding, etc. of the parts in the set and assembling of the parts and packaging.
PD (peritoneal dialysis)	A treatment available for patients with kidney disease. The primary components of peritoneal dialysis are the dialysis solution (dialysate) and its container, fill and drain lines, catheter, and drainage bag. In peritoneal dialysis the patient introduces dialysate into the body through the fill line and a surgically implanted catheter. The peritoneum removes waste products from the blood and discharges them into a drain line that connects to a drainage bag.
Plasticisers	A substance which when added to a material, usually a plastic, produces a product which is flexible, resilient and easier to handle.
Producer of plastic raw material	Company that produces the plastic raw material. The production process comprises polymerisation and compounding. Compounding is the process of mixing the basic polymer with additives.
Product	A set or parts of sets and their primary packaging in the application for the Swan label.
Set	Consist of several parts, i.e. a bag, that contains the pharmaceutical, tubing and a catheter for transporting the pharmaceutical into the patient.

Supplier

Company that supplies goods or services to the manufacturer. The definition is based on the definition in ISO 9000:2000.

## Appendix 1 Applicant's declaration

For use in applications for a licence for a Swan label for peritoneal dialysis and intravenous sets. In signing this form, the applicant undertakes to keep the submitted information updated as long as the criteria are valid.

Name on the product: \_\_\_\_\_

### 1. Description of the product

Part in the product	Function	Weight of part (g)	Manufacturer	Material	Legislation

### 2. Recycling system

The relevant national regulations, laws and/or industry-wide agreements on recycling systems for products and packaging are fulfilled in the Nordic countries in which the Swan-labelled products are marketed.

### 3. EU Scientific committee SCENIHR

The product follows the recommendations from the EU scientific committee SCENIHR.

(See [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/04\\_scenihhr\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/04_scenihhr_en.htm))

## Signature

We declare that the requirements have been met and that the information provided matches reality.

---

Date and place

---

Company

---

Signature, contact person

---

Clarification of name

---

Phone

In case of a change in personnel, a new declaration must be submitted to Nordic Ecolabelling.

## Appendix 2 Manufacturer's declaration

For use in applications for a licence for a Swan label for peritoneal dialysis and intravenous sets. In signing this form, the manufacturer undertakes to keep the submitted information updated for the validity period of the criteria.

Name on the product: \_\_\_\_\_

### 1. Plastics and packaging

The product and packaging do not consist of chlorinated plastics such as PVC.

Part in the product	Name of plastic raw material	Name and location of supplier of the plastic raw material

Are any additives added to the plastic raw material in the manufacturing? Yes \_ No \_

- If yes, complete and sign the form in Appendix 3 and make sure the supplier of the additives complete and sign the form in Appendix 4.

### 2. Adhesives

Are any adhesives used in the product? Yes \_ No \_

If yes fill in the table:

Name of adhesive	Name of adhesive supplier

- If yes, make sure the supplier of the adhesive completes and signs the form in Appendix 4.





## Appendix 4 Requirements for plasticisers and other additives in the plastic material and for adhesives

This form is for use by suppliers of plasticisers and other additives in the plastic as well as adhesives for documenting Nordic Ecolabelling's requirements for peritoneal dialysis- and intravenous sets.

The documentation may be submitted directly to Nordic Ecolabelling. In signing this form, the supplier or manufacturer undertakes to keep the submitted information updated for the validity period of the criteria.

Nordic Ecolabelling is, however, entitled to seek information on the full composition of the chemical from the chemical manufacturer/supplier in order, where necessary, to check the content of the chemical.

The final section of the criteria document contains explanations and definitions of words and terms that may be difficult to interpret. If you are unsure, always check the Swan definition.

Please complete the form for chemical identification:

Country	Trade name (where applicable fill more than one name)	Group designation, where applicable	Product number, where applicable
Internationally			
Sweden			
Norway			
Iceland			
Finland			
Denmark			

Enclosed material safety data sheet or other technical data sheet.

Function of the chemical:

Plasticiser  Other additive, specify: \_\_\_\_\_

Adhesive

### 1 Endocrine disruption

The chemical is not regarded as having potential for endocrine disruption in accordance with official lists published in any Nordic country or the EU.

(See [http://europa.eu.int/comm/environment/docum/01262\\_en.htm](http://europa.eu.int/comm/environment/docum/01262_en.htm))

Note that the EU list of substances causing endocrine disruption has a class 3C, in which the assessment is: "No scientific basis for inclusion in list. Data available indicating no scientific basis for inclusion in list." These substances are not regarded as causing endocrine disruption.

## 2 Hazardous to health and the environment

The chemical is not classified in any of the following hazard categories (with applicable risk phrases in parenthesis):

carcinogenic with T (R45, R49)

carcinogenic with Xn (R40)

reproductive toxic with T (R60, R61)

reproductive toxic with Xn (R62, R63)

causing heritable genetic damage with T (R46)

causing heritable genetic damage with Xn (R68)

very toxic with T+ (R26, R27, R28 R39)

toxic with T (R23, R24, R25, R39, R48)

harmful with Xn (R40, R48)

allergenic with Xn (R42)

allergenic with Xi (R43)

environmentally hazardous with N (R50, R50/53, R51/53, R59)

environmentally hazardous without N (R52/53, R52, R53)

in accordance with current rules in Denmark, Finland, Iceland, Norway and Sweden. These rules are based on EU Directive 1999/45/EC with subsequent amendments and revisions.

### Signature

We declare that the requirements have been met and that the information provided is accurate and correct:

Supplier: \_\_\_\_\_

Producer: \_\_\_\_\_

Company name:	
Address:	
Tel./Fax:	Date:
E-mail:	
Signature:	
Name (printed):	

## **Appendix 5 Procedures and instructions (M1-M5)**

This form is to be used to document the fact that the manufacturer can meet Nordic Ecolabelling's requirements as long as the licence is valid.

If the applicant wishes to adjust the procedures (without altering the contents) to achieve a better fit to management systems already established in the company, he/she may obtain this appendix electronically in an editable format from Nordic Ecolabelling.

Physical location of copy of application and any other information used in the application: \_\_\_\_\_

Physical location of journal material for annual reports (see M4): \_\_\_\_\_

\_\_\_\_\_

### **1 Legislation and authorities (M1)**

Name of supervisory environmental authority: \_\_\_\_\_

Address: \_\_\_\_\_

Contact, where applicable: \_\_\_\_\_

Name of supervisory working environment authority: \_\_\_\_\_

Address: \_\_\_\_\_

Contact, where applicable: \_\_\_\_\_

### **2 Organisation and responsibility (M2)**

Contact for Nordic Ecolabelling: \_\_\_\_\_

Person responsible for environmental matters: \_\_\_\_\_

Person responsible for quality matters: \_\_\_\_\_

Person responsible for marketing matters: \_\_\_\_\_

Person responsible for day-to-day operations: \_\_\_\_\_

In the event of changes in areas of responsibility, the contact must notify Nordic Ecolabelling as soon as the change has been implemented.

### **3 Procedure for documenting, processing and reporting non-conformities, claims/complaints and changes (M4)**

The purpose of this procedure is to ensure that the Swan label requirements are met in the event of non-conformities, complaints and changes.

The procedure covers all production of ecolabelled products the manufacturer.

- The contact is responsible for documenting and processing unforeseen non-conformities and planned changes and for all reporting to Nordic Ecolabelling. This responsibility may be delegated to others.
- \_\_\_\_\_ (name) is responsible for documenting and processing claims/complaints. This responsibility may be delegated to others.

#### **Changes**

- In the event of changes to the information on which the original application for a Swan label was based, the contact must notify Nordic Ecolabelling in writing before the change is implemented. This might, for example, involve changes of the ecolabelled product or changes in the law.
- The contact determines whether a change affects compliance with the criteria.
- In the letter to Nordic Ecolabelling, the contact must state the nature of the change and how it affects the ecolabelling criteria. In addition, the contact must attach a completed and signed application form for a change/extension of the licence.
- The change is implemented only when a reply has been received from Nordic Ecolabelling. The contact must ensure that all correspondence with Nordic Ecolabelling is documented and filed together with the original application.

#### **Non-conformities**

- In the event of non-conformities that affect compliance with the ecolabelling criteria, the contact must notify Nordic Ecolabelling in writing immediately after the non-conformity has taken place.
- The contact determines first of all whether or not a non-conformity affects compliance with the criteria. Nevertheless, the contact must always file a non-conformity report if he/she is requested to do so by Nordic Ecolabelling.
- The non-conformity report contains a description of the nature of the non-conformity, an account of its scope, a description of how the non-conformity occurred, a description of what steps have been taken to remedy the non-conformity and a plan for avoiding similar non-conformities in the future.
- If the plan encompasses changes in relation to the original application, the contact will treat this in the same way as a planned change.

- The contact must ensure that all correspondence with Nordic Ecolabelling is documented and filed together with the original application.

#### **Complaints**

- In the event of written complaints/claims, the person with responsibility for this area will reply to the party making the complaint. The reply must contain a clear decision on the complaint/claim, where applicable with information about compensation and a clear specification of the reasons underlying the decision.
- The responsible person will ensure that all written complaints/claims are documented and filed together with the original application.
- If the complaint results in changes in the internal working method, the contact for Nordic Ecolabelling must be notified.

#### **4 Procedures for ensuring traceability (M5)**

The purpose of this procedure is to ensure that ecolabelled products are kept separate from products not labelled.

The procedure covers all production by the manufacturer.

- The contact for Nordic Ecolabelling is responsible for ensuring that products that are to be eco-labelled are marked clearly so that they can be kept separate from other products. This responsibility may be delegated to others. For this purpose, the following information follows the product throughout the manufacturing:
  - Used plastic material and name of supplier
  - Information to the effect that PVC must not be used as material

Production sheet or similar.

#### **5 Procedures for recording the journal (M4)**

The purpose of this procedure is to ensure that journals are recorded.

The procedure covers all production of ecolabelled products by the manufacturer.

The Nordic Ecolabelling contact is responsible for the recording of the journal. This responsibility may be delegated to others.

- The contact investigates whether any changes have occurred in relation to the application and whether the ecolabelling criteria are still fulfilled.
- If such major changes have occurred that the criteria are no longer fulfilled, a non-conformity is involved (see point 2).
- The contact ensures that the journal material, such as invoices, reports, measurements or excerpts from the accounting system, and operating journals

are stored together with the original application for checking by Nordic Ecolabelling so long as the ecolabelling licence remains in force.

## **Appendix 6 Marketing of peritoneal dialysis and intravenous sets (M6)**

We hereby certify that we are well acquainted with the regulations governing the use of the Nordic Swan ecolabel, as detailed in "Regulations for Nordic Ecolabelling" 12 December 2001 or later versions. We agree to follow these regulations when marketing the Swan-labelled health care product.

Further, we confirm that we are familiar with the criteria document regarding the Swan labelling of peritoneal dialysis- and intravenous sets.

We undertake to advise those individuals within the company involved in marketing the Swan-labelled health care product of the criteria for the Swan labelling of peritoneal dialysis- and intravenous sets and "Regulations for Nordic Ecolabelling" 12 December 2001 or later versions.

---

Date and place	Company
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Signature, contact person

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Clarification of name	Phone
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Signature, marketing director

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Clarification of name	Phone
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In case of a change in personnel, a new declaration must be submitted to Nordic Ecolabelling