Nordic Ecolabelling for

Disposable bags, tubes and accessories for health care



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Nordic Ecolabelling

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Addresses

In 1989, the Nordic Council of Ministers decided to introduce a voluntary official ecolabel, the Nordic Swan Ecolabel. These organisations/companies operate the Nordic Ecolabelling system on behalf of their own country's government. For more information, see the websites:

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It may be quoted from provided that Nordic Ecolabelling is stated as the source.

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What is a Nordic Swan Ecolabelled disposable product for health care?

A Nordic Swan Ecolabelled disposable product for health care fulfils strict chemical requirements. The products do not contain PVC or harmful plasticisers. For many disposable health care products there are safe and economically viable alternatives to PVC and phthalates. EU legislation in the area is extensive and imposes strict requirements as to the safety of the products.

Why choose the Nordic Swan Ecolabel?

- Manufacturers and distributers may use the Nordic Swan Ecolabel trademark for marketing. The Nordic Swan Ecolabel is a very well-known and well-reputed trademark in the Nordic region.
- The Nordic Swan Ecolabel is a simple way of communicating environmental work and commitment to customers.
- The Nordic Swan Ecolabel clarifies the most important environmental impacts and thus shows how a company can cut emissions, resource consumption and waste management.
- Environmentally suitable operations prepare the products for future environmental legislation.
- Nordic Ecolabelling can be seen as providing a business with guidance on the work of environmental improvements.
- The Nordic Swan Ecolabel not only covers environmental issues but also quality requirements, since the environment and quality often go hand in hand. This means that a Nordic Swan Ecolabel licence can also be seen as a mark of quality.

What can carry the Nordic Swan Ecolabel?

Disposable products that can be labelled must be single-use products included under the Regulation (EU) 2017/745 on medical devices with subsequent amendments and adaptations and/or EU Medicinal Products Directive (2001/83/EC) as applicable. It is emphasized that Nordic Ecolabelling do not put any requirements to the medicinal product, but it is important that the medicinal product is according to the regulations and relevant directives.

The disposable product must be an alternative to products of softened PVC on the market. Products that can be labelled are:

- intravenous (IV) infusion treatment
- blood bags
- peritoneal dialysis (PD) treatment
- treatment of urinary retention and incontinence
- ostomy pouches and accessories for treatment following ileostomy, colostomy, or ureterostomy surgery

Other relevant disposable health care products that are not mentioned above may be included in the product group if they are an alternative to products made

of softened PVC and if they are governed by the aforementioned regulation and directive. Nordic Ecolabelling will decide which new products may be included in the product group.

Some disposable products for medical use that are not included in this criteria can be labelled under the criteria for sanitary products, for example plasters, compresses, mattress covers/protectors, draw sheets, surgical gowns, patient gowns/patient covers, surgical masks and caps.

How to apply

Application and costs

For information about the application process and fees for this product group, please refer to the respective national web site. For addresses see page 2.

What is required?

The application must consist of an application form/web form and documentation showing that the requirements are fulfilled.

Each requirement is marked with the letter O (obligatory requirement) and a number. All requirements must be fulfilled to be awarded a licence.

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

🔑 Requirement checked on site

All information submitted to Nordic Ecolabelling is treated confidentially. Suppliers can send documentation directly to Nordic Ecolabelling, and this will also be treated confidentially.

Licence validity

The Nordic Swan 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.

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.

Queries

Please contact Nordic Ecolabelling if you have any queries or require further information. See page 2 for addresses. Further information and assistance (such as calculation sheets or electronic application help) may be available. Visit the relevant national website for further information.

1 General requirements

O1 Description of the product and production process

The applicant must provide the following information about the product and the production process:

- Trade name of the product
- Function of the product
- That the product is included in the regulation 2017/745 and/or 2001/83/EC
- Information about the different components and their function (like bag for solutions, tubes, connectors etc.) and what materials* the different components are made of.
- A flowchart showing the production of the product, including information on what components are bought from external manufacturers and what processes are done externally and internally

**materials can be different plastics like PE, PET, PA as well as other kind of materials like silicone.*

✉ Description in accordance with the requirement and flowchart that shows the production of the product (from the components to finalized product). Appendix 1 (applicant's declaration) and appendix 2 (for the manufacturer of the product) can be used.

2 Environmental and health requirements

This chapter covers both requirements to the materials in the product, and to chemicals added to the plastic material or used in or on the different components or product, like adhesive.

2.1 Materials

O2 Halogenated plastics

Halogenated plastics such as PVC are not allowed in the product, packaging or transport packaging.

Packaging refers to any inner and outer packaging of the product.

✉ Duly completed and signed appendix 2 by the manufacturer of the product. Equivalent documentation can be approved.

O3 Latex

Latex (natural) are not allowed in the product or packaging.

✉ Duly completed and signed appendix 2 by the manufacturer of the product. Equivalent documentation can be approved.

O4 Silicone

For products made of silicone, like a tube or catheter:

Octamethyl cyclotetrasiloxane, D4, (CAS 556-67-2), decamethyl cyclopentasiloxane, D5, (CAS 541-02-6) and dodecamethyl cyclohexasiloxane, D6, (CAS 540-97-6) must not form part of the silicone material. The requirement does not apply to D4, D5 and D6 contained as impurities* up to a limit of 100 ppm.

For small parts of silicone, like sealing:

Octamethyl cyclotetrasiloxane, D4, (CAS 556-67-2), decamethyl cyclopentasiloxane, D5, (CAS 541-02-6) and dodecamethyl cyclohexasiloxane, D6, (CAS 540-97-6) must not form part of the silicone material. The requirement does not apply to D4, D5 and D6 contained as impurities* up to a limit of 1000 ppm.

**Impurities of D4, D5 and D6 are defined as residual products from the raw material production that can be found in the silicone material*

✉ Duly completed and signed: Appendix 4, Silicones in the product or Appendix 5 for small parts of silicone. Equivalent documentation can be approved.

2.2 Chemicals

The requirements apply to:

- Plasticisers and other additives like colourants/pigments and antioxidants added to the plastic to give the plastic different properties
- Adhesive used in or on the various parts/components of the product

The requirements apply to additives added to soft and hard plastic, as well as any other material that might be a part of the product, like rubber and silicone.

The requirements do not apply to rest monomers in the plastic material from the production process of the plastic. For D4, D5 and D6 as residual products from the production of silicone there is an own requirement, see O4.

No requirements are imposed on chemicals used for maintenance of machines or in the production processes (such as lubricants, cleaning chemicals etc.) without being added to the plastic material, unless otherwise stated.

No requirements are imposed on chemicals used on the transport packaging, for instance adhesives and printing inks used on a cardboard box for packaging of the final product.

The requirements in the criteria document and accompanying appendices apply to all ingoing substances in the chemical product, but not impurities unless stated otherwise in the requirements. Ingoing substances and impurities are defined below:

Ingoing substances: All substances in the chemical product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine) are also regarded as ingoing substances.

Impurities: Residuals, pollutants, contaminants etc. from production, including production of raw materials that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg).

Please note that the definition on ingoing substances and impurities only apply to requirement O6 and O7. O5 concerns the classification of the chemical product and not the classification of ingoing substances in the chemical product.

Information can be sent directly to Nordic Ecolabelling. Nordic Ecolabelling will provide confidentiality agreements if requested.

O5 Chemical products, classification

The requirement applies to:

- Plasticisers and other additives like colourants/pigments and antioxidants added to the plastic material
- Adhesives used in or on the various parts/components of the product

The plasticisers, other additives and adhesives cannot be classified according to table 1:

Table 1. Classification

Classification under CLP Regulation (EC) No 1272/2008		
Hazard class	Category	Hazard code
Hazardous to the aquatic environment*	Aquatic Acute 1 Aquatic Chronic 1 Aquatic Chronic 2 Aquatic Chronic 3 Aquatic Chronic 4	H400 H410 H411 H412 H413
Carcinogenic	Carc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity	Muta. 1A eller 1B Muta. 2	H340 H341
Reproductive toxicity	Repr. 1A eller 1B Repr. 2 Lact.	H360 H361 H362
Acute toxicity	Acute Tox 1 or 2 Acute Tox 1 or 2 Acute Tox 1 or 2 Acute Tox 3 Acute Tox 3 Acute Tox 3	H300 H310 H330 H301 H311 H331
Specific target organ toxicity	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Aspiration hazard	Asp. Tox. 1	H304
Allergenic	Resp. sens 1 or Skin sens 1	H334 H317

**There is an exception of up to 0,1 % by weight of additives classified as hazardous for the environment (the pharmaceutical inside as well as box for secondary packaging and transport packaging shall not be included in the weight of the product)*

✉ Safety data sheet in accordance with current European legislation and/or duly completed and signed appendix 3. The appendix can be filled out by the manufacturer of the ecolabelled product, the material supplier or the chemical supplier.

Equivalent documentation with date and signature can also be approved.

O6 Chemical substances – CMR

The requirement applies to:

- Plasticisers and other additives like colourants/pigments and antioxidants added to the plastic material
- Adhesives used in or on the various parts/components of the product

Ingoing substances (apart from impurities) in the plasticisers, other additives and adhesives must not be classified as carcinogenic (Carc), mutagenic (Mut) and/or toxic for reproduction (Rep) according to CLP Regulation (EC) No 1272/2008 (see Table 2).

For definition of ingoing substances and impurities, see beginning of the section 2.2 Chemicals.

Table 2. Classification of CMR substances

Classification in line with CLP Regulation (EC) No 1272/2008	
Hazard class and category	H phrases (Code)
Carcinogenic Carc. 1A/1B Carc. 2	 H350 H351*
Mutagenic Muta. 1A/B Muta. 2	 H340 H341
Toxic for reproduction Repr. 1A/1B Repr. 2	 H360, H361 H362

** Exception is given for 2-component adhesives with isocyanates (classified H351), if the workers are not exposed during the production of the product and the isocyanates are cured in the finished product. Legislation for working environment must be fulfilled.*

✉ Safety data sheet in accordance with current European legislation and/or duly completed and signed appendix 3. The appendix can be filled out by the manufacturer of the ecolabelled product, the material supplier or the chemical supplier.
Equivalent documentation with date and signature can also be approved.

O7 Chemical substances – other excluded substances

The requirement applies to:

- Plasticisers and other additives like colourants/pigments and antioxidants added to the plastic material
- Adhesives used in or on the various parts/components of the product

Ingoing substances (apart from impurities) in the plasticisers, other additives and adhesives must not be from the list below.

For definition of ingoing substances and impurities, see beginning of the section 2.2 Chemicals.

List of excluded substances

- Substances of very high concern (SVHC)*
- Substances on the Candidate List**

D4, D5 and D6 in silicone polymers, see O4.

- Substances that have been evaluated in the EU to be PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative)***

- Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects****
- Phthalates*****

** Substances that meet the criteria in article 57 of the REACH Regulation*

***The Candidate List can be found on the ECHA website: http://echa.europa.eu/candidate-list-table*

****PBT and vPvB in accordance with the criteria in Annex XIII of REACH*

**** *Substances considered to be potential endocrine disruptors in category 1 or 2, see following link: http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf, see appendix L*

******Esters of phtalic acid (orthophthalic acid / phthalic acid /1,2-benzenedicarboxylic acid). The prohibition does not include polyethylene terephthalate (PET).*

✉ Safety data sheet in accordance with current European legislation and/or duly completed and signed appendix 3. The appendix can be filled out by the manufacturer of the ecolabelled product, the material supplier or the chemical supplier.
Equivalent documentation with date and signature can also be approved.

3 Safety requirement

O8 Safety

Both product and parts must be safe to use and function well according to the EU Medicinal Products Directive (2001/83/EC) and / or the EU Medical Devices Regulation (2017/745) with subsequent amendments and adaptations, as applicable.

✉ Medical device: Copy of the approval / certificate from a notified body.
✉ Medicinal product: Copy of the market authorisation from the reference member state or national authority.

4 Quality and regulatory requirements

To ensure that Nordic Ecolabelling requirements are fulfilled, the following procedures must be implemented.

O9 Responsible person and organisation

The company shall appoint individuals who are responsible for ensuring the fulfilment of the Nordic Ecolabelling requirements, for marketing and for finance, as well as a contact person for communications with Nordic Ecolabelling.

✉ Organisational chart showing who is responsible for the above.

O10 Documentation

The licensee must archive the documentation that is sent in with the application.

🔑 Checked on site as necessary.

O11 Quality of the disposable article

The licensee must guarantee that the quality of the Nordic Swan Ecolabelled product does not deteriorate for its defined shelf-life during the validity period of the licence.

✉ Procedures for archiving claims and, where necessary, dealing with claims and complaints regarding the quality of the Nordic Swan Ecolabelled disposable article.

🔑 The claims archive is checked on site.

O12 Planned changes

Written notice must be given to Nordic Ecolabelling of planned changes in products and markets that have a bearing on Nordic Ecolabelling requirements.

✉ Procedures detailing how planned changes in products and markets are handled.

O13 Unplanned nonconformities

Unplanned nonconformities that have a bearing on Nordic Ecolabelling requirements must be reported to Nordic Ecolabelling in writing and journalled.

✉ Procedures detailing how unplanned nonconformities are handled.

O14 Traceability

The licensee must be able to trace the Nordic Swan Ecolabelled disposable product in the production.

✉ Description of/procedures for the fulfilment of the requirement.

O15 Legislation and regulations

The licensee shall ensure compliance with all applicable laws and provisions at all production facilities for the Nordic Swan Ecolabelled product, e.g. with regard to safety, working environment, environmental legislation and site-specific terms/permits.

✉ Signed application form.

Regulations for the Nordic Ecolabelling of products

When the Nordic Swan Ecolabel is used on products the licence number shall be included.

More information on graphical guidelines, regulations and fees can be found at www.nordic-ecolabel.org/regulations/

The products may also be provided with following additional and explanatory text (replace “peritoneal dialysis” with correct term for other product categories):

- Disposable peritoneal dialysis product – does not contain PVC or
- The Nordic Swan Ecolabel requirements cover the packaging, bag and accessories

Follow-up inspections

Nordic Ecolabelling may decide to check whether the disposable product for health care fulfils Nordic Ecolabelling requirements during the licence period. This may involve a site visit, random sampling or similar test.

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

History of the criteria

Nordic Ecolabelling adopted version X.X of the criteria for XX on DAY MONTH YEAR. The criteria are valid until DAY MONTH YEAR.

Appendix 1 Applicant's declaration

Trade name of the product(s): _____

Type of product:

Blood bag ☐

Intravenous (IV) infusion treatment ☐

Peritoneal dialysis Treatment ☐

Treatment of urinary retention and incontinence ☐

Ostomy pouches and accessories for treatment following ileostomy, colostomy or ureterostomy surgery ☐

Description of the product

Parts and packaging	Function	Weight of part (g)*	Manufacturer (if external)	Legislation***
				☐ Medicinal product ☐ Medical device
				☐ Medicinal product ☐ Medical device
				☐ Medicinal product ☐ Medical device
				☐ Medicinal product ☐ Medical device
				☐ Medicinal product ☐ Medical device
				☐ Medicinal product ☐ Medical device
				☐ Medicinal product ☐ Medical device
				☐ Medicinal product ☐ Medical device

* *Approximate weight in grams.*

** *The implementation of the EU Medicinal Products Directive (2001/83/EC) and the Regulation (EU) on Medical Devices (2017/745), with subsequent amendments and adaptations.*

O8 Safety

Are the product and/or parts according to the EU Medicinal Products Directive (2001/83/EC) and / or the EU Medical Devices Regulation (2017/745) with subsequent amendments and adaptations. ☐ Yes ☐ No

Please attach:

- Medical device: Copy of the approval / certificate from a notified body.
- Medicinal product: Copy of the market authorisation from the reference member state or national authority.

Signature

Date and place:	Name of the company:
Responsible person:	Signature of responsible person:

Appendix 2 Description of the product and production process

For the requirements O1, O2 and O3

To be completed by the manufacturer of the ecolabelled product

Name of the product(s): _____

1. Production process

Please attach a flowchart showing the production of the product, including information on what components are bought from external manufacturers and what processes are done externally and internally**.**

2. Materials in the product

O2 Halogenated plastics

Does the product or packaging, including transport packaging contain halogenated plastic? ☐ Yes ☐ No

O3 Latex

Does the product or packaging contain latex (natural)? ☐ Yes ☐ No

Please fill in the table below:

Materials in the product

Part of the product and packaging	Plastic material*

* *Indicated as for instance PP, PE, PET and so on*

3. Chemicals

Additives

Are any additives* added to the plastic raw material during the manufacturing process? ☐ Yes ☐ No

**additives refer to for instance plasticisers, pigments and antioxidants*

If yes, please state the additives in the table below:

Additives in the plastic

Part/packaging	Name of plastic raw material	Additives (chemical name and or CAS No.)	Function

For documentation of the chemical requirements to additives, please use appendix 3.

Adhesives

Is adhesive used in or on the various parts/components of the product? ☐ Yes ☐ No

If yes, state the name of the adhesive:_____

For documentation of the chemical requirements to adhesives, please use appendix 3.

Signature

Date and place:	Name of the producer of the disposable product for health care:
Responsible person:	Signature of responsible person:

Appendix 3 Plasticisers, other additives and adhesives

For requirements O5, O6 and O7

Filled out by:

Manufacturer of the ecolabelled product: ☐

Material supplier: ☐

Chemical supplier: ☐

Name of the chemical and purpose of use:

_____

The requirements apply to all ingoing substances in the chemical product (plasticisers, other additives and adhesives), but not impurities unless stated otherwise in the requirements. Ingoing substances and impurities are defined below:

Ingoing substances: All substances in the chemical product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine) are also regarded as ingoing substances.

Impurities: Residuals, pollutants, contaminants etc. from production, incl. production of raw materials that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg).

O5 Chemical product - classification

Is the plasticiser, additive or adhesive classified according to the table below?

Classification under CLP Regulation (EC) No 1272/2008			
Hazard class	Category	Hazard code	
Hazardous to the aquatic environment	Aquatic Acute 1 Aquatic Chronic 1 Aquatic Chronic 2 Aquatic Chronic 3 Aquatic Chronic 4	H400 H410 H411 H412 H413	☐ Yes ☐ No
Carcinogenic	Carc. 1A or 1B Carc. 2	H350 H351	☐ Yes ☐ No
Germ cell mutagenicity	Muta. 1A eller 1B Muta. 2	H340 H341	☐ Yes ☐ No
Reproductive toxicity	Repr. 1A eller 1B Repr. 2 Lact.	H360 H361 H362	☐ Yes ☐ No
Acute toxicity	Acute Tox 1 or 2 Acute Tox 1 or 2 Acute Tox 1 or 2 Acute Tox 3 Acute Tox 3 Acute Tox 3	H300 H310 H330 H301 H311 H331	☐ Yes ☐ No

Specific target organ toxicity	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373	☐ Yes ☐ No
Aspiration hazard	Asp. Tox. 1	H304	☐ Yes ☐ No
Allergenic	Resp. sens 1 or Skin sens 1	H334 H317	☐ Yes ☐ No

O6 Chemical substances - CMR

Are ingoing substances (apart from impurities) in the plasticiser, additive and adhesive classified as carcinogenic (Carc), mutagenic (Mut) and/or toxic for reproduction (Rep) according to CLP Regulation (EC) No 1272/2008 (see table below):

Classification of CMR substances

Classification in line with CLP Regulation (EC) No 1272/2008		
Hazard class and category	H phrases (Code)	
Carcinogenic Carc. 1A/1B Carc. 2	 H350 H351*	 ☐ Yes ☐ No ☐ Yes ☐ No
Mutagenic Muta. 1A/B Muta. 2	 H340 H341	 ☐ Yes ☐ No ☐ Yes ☐ No
Toxic for reproduction Repr. 1A/1B Repr. 2	 H360, H361 H362	 ☐ Yes ☐ No ☐ Yes ☐ No

** Exception is given for 2-component adhesives with isocyanates (classified H351, if the workers are not exposed during the production of the product) and the isocyanates are cured in the finished product. Legislation for working environment must be fulfilled.*

O7 Chemical substances – other excluded substances

Are ingoing substances (apart from impurities) in the plasticiser, additive and adhesive from the list below:

Substances of very high concern (SVHC)* ☐ Yes ☐ No

Substances on the Candidate List** ☐ Yes ☐ No

For D4, D5 and D6 in silicone polymers, see O4.

Substances that have been evaluated in the EU to be PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative)*** ☐ Yes ☐ No

Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects**** ☐ Yes ☐ No

Phthalates***** ☐ Yes ☐ No

** Substances that meet the criteria in article 57 of the REACH Regulation*

***The Candidate List can be found on the ECHA website: http://echa.europa.eu/candidate-list-table*

****PBT and vPvB in accordance with the criteria in Annex XIII of REACH*

**** *Substances considered to be potential endocrine disruptors in category 1 or 2, see following link: http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf, see appendix L*

******Esters of phtalic acid (orthophthalic acid / phthalic acid /1,2-benzenedicarboxylic acid). The prohibition does not include polyethylene terephthalate (PET).*

Signature

Date and place:	Name of company:
Responsible person:	Signature of responsible person:

Appendix 4 Silicone in the product

For requirement O4

Trade name of the silicone material:_____

Do octamethylcyclotetrasiloxane, D4, (CAS 556-67-2), decamethyl cyclopentasiloxane, D5, (CAS 541-02-6) and/or dodecamethyl cyclohexasiloxane,D6 (CAS 540-97-6) form part of the product? ☐ Yes ☐ No

If yes, is the amount of D4, D5 and D6 as impurities* in concentrations below 100 ppm? ☐ Yes ☐ No

**The requirement does not apply to D4, D5 and D6 contained as impurities. Impurities are defined as residual products from the raw material production that can be found in the silicone material in concentrations below 100 ppm.*

Signature

Date and place:	Name of company:
Responsible person:	Signature of responsible person:

Appendix 5 Silicone in small parts

For requirement O4

Trade name of the silicone material:_____

Do octamethylcyclotetrasiloxane, D4, (CAS 556-67-2), decamethyl cyclopentasiloxane, D5, (CAS 541-02-6) and/or dodecamethyl cyclohexasiloxane,D6 (CAS 540-97-6) form part of the product? ☐ Yes ☐ No

If yes, is the amount of D4, D5 and D6 as impurities* in concentrations below 1000 ppm? ☐ Yes ☐ No

**The requirement does not apply to D4, D5 and D6 contained as impurities. Impurities are defined as residual products from the raw material production that can be found in the silicone material in concentrations below 1000 ppm.*

Signature

Date and place:	Name of company:
Responsible person:	Signature of responsible person: