Nordic Ecolabelling for

Medical devices and medicinal products in plastic and silicone

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Nordic Ecolabelling

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Contact information

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:

Denmark

Ecolabelling Denmark

www.svanemaerket.dk

Iceland

Ecolabelling Iceland

www.svanurinn.is

Finland

Ecolabelling Finland

www.joutsenmerkki.fi

Norway

Ecolabelling Norway

www.svanemerket.no

Sweden

Ecolabelling Sweden

www.svanen.se

1 Environmental communication guideline for Nordic Swan Ecolabel Medical devices and medicinal products in plastic and silicone

A Nordic Swan Ecolabel Medical device in plastic or silicone does not contain PVC or phthalates. The products fulfil strict chemical requirements for surface treatment, adhesive and additives in plastic and silicon. The packaging must be of materials and be designed to promote recycling. EU legislation in the area is extensive and imposes strict requirements as to the safety of the products.

Nordic Swan Ecolabel Medical devices and medicinal products in plastic and silicone:

- Are free from halogenated plastics (e.g. PVC) and rubbers.
- Meet strict environmental and health requirements for substances in materials, adhesives and surface treatments. For example, the following are not allowed:
    - Phthalates
    - PFAS
    - Bisphenols
    - Identified and potential endocrine disruptors on up-to-date lists from EU and national authorities
- Meet strict limits for the number of impurities of the siloxanes D4, D5 and D6 in silicone.
- Have packaging design and materials that promote recycling.
- Products mainly made of silicone (min. 80 w%) have reduced emissions of dust and chlorides to air and copper and zinc to water during manufacturing.

2 What can carry the Nordic Swan Ecolabel?

Product group definition

Products that may carry the Nordic Swan Ecolabel are mainly (min. 90 w%) made of plastic or silicone and are for storage, transfer or transport of fluid, gas or medicine; or for preventing leakage of fluids from the body. The products must be included under the Regulation (EU) 2017/745 on medical devices or EU Medicinal Products Directive (2001/83/EC). The products can either be single-use or reusable.

Products included are:

Masks: Masks or other devices used to deliver for example oxygen and anaesthetic gases: Oxygen mask, anaesthesia mask, laryngeal mask, oxygen halter, and breathing balloon set.

Flexible tubes: Flexible tubes used for removal of gas or fluids, maintaining open airways, delivering oxygen, other gases, medication or nutrition: Urine catheter, vein catheter, umbilical catheter, intravenous infusion treatment, intestinal tube, gastric tube, duodenal tube, tracheal tube, pharyngeal tube, nasal tube, suction hose, and drainage.

Bags: Bags or pouches used for storage and transfer of fluids: Blood bag, urine bag, drainage bag, suction bag, ostomy pouch, and dialysis treatment bag.

Plugs: Utilities used for preventing leakage from the body: Anal plug, continence support, and prolapse ring.

Syringes: Includes empty syringes and syringes prefilled with saline or water.

The fluid, gas or medicine that are stored, transferred or transported are not covered by the requirements of these criteria.

If a product is a combination of different subcomponents mentioned above, it is also included within these criteria. For example, bags, catheters and tubes in a peritoneal dialysis (PD) treatment set.

Accessories as clamps, stoppers, connectors, caps etc. can be approved as stand-alone products, but only if they originally are a part of and sold in connection with an ecolabelled main product.

In addition to those specified above, relevant medical devices and medicinal products in plastic and silicone may be included in the product group upon request. This applies only to products mainly (min. 90 w%) made of plastic or silicone and are for storage, transfer and transport of fluid, gas or medicine; or for preventing leakage of fluids from the body, and which are included under the Regulation (EU) 2017/745 on medical devices or EU Medicinal Products Directive (2001/83/EC). Nordic Ecolabelling will decide which new products may be included in the product group.

Some products for medical use, not included in these criteria, can be certified with Nordic Swan Ecolabel under the criteria for “Protective and Absorbent Hygiene Products”, for example plasters, compresses, mattress covers/protectors, draw sheets, surgical gowns, patient gowns/patient covers, surgical masks, and caps.

3 How to read this criteria document

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:

- Upload documentation.
- Requirement checked on site.

To be awarded a Nordic Swan Ecolabel licence:

- All obligatory requirements must be fulfilled.
- Nordic Ecolabelling must inspect the 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.

4 Requirements

4.1 Definitions

Terms	Definition
Ingoing substances	All substances* in the chemical product/additive regardless of amount, including additives (e.g., preservatives and stabilizers) in the raw materials. Substances released from ingoing substances (e.g., biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances. ** N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance (Unknown or Variable composition, Complex reaction products or of biological materials) are also regarded separately, and all known constituents must be regarded.*
Impurities *(See additional information about ingoing substances and impurities below this table)*	Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials, that remain in the chemical product or additive in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%). *Examples of impurities: Background environmental pollutants from feedstock, as well as contaminants and residues from production such as reactants (incl. monomers), reagents, catalysts, by-products, scavengers, detergents for production equipment, carry-over from other or previous production lines.* Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the chemical product or additive.
Surface treatment	Surface treatment is usually added to improve the function of the product. This could for example be lubricants and coatings whose main purpose is to ease insertion or improve the user experience. The surface treatment is often used as a barrier between the materials in the product and the human body or medicinal liquids.
Primary packaging	Primary packaging means the packaging of the product that is necessary until the point of user. In the case of sterile products, primary packaging is designed to maintain the sterility of the product resulting in one piece of the specific product per primary packaging. Non-sterile products can be packed in primary packaging per product, in a certain number of products or without any primary packaging. It depends on the product types and their need for protection.
Secondary packaging	Secondary packaging means the packaging of a certain number of products in their primary packaging (if used) for protection during transport and storage.
Tertiary packaging	Tertiary packaging means the outer layer of packaging in which the product is distributed during their initial dispatch from the manufacturer of the product. Auxiliary packaging as wrapping film etc. for transportation pallets are excluded. Other packaging used in downstream distribution, including transport between distribution centres, retailers, or final customers is excluded.
Packaging component	A component is a component that is easily separable from other components without the use of tools. Examples are boxes, bags and detachable lids.
Recycled material	Recycled material is defined in the requirement according to ISO 14021, which applies the following two categories: “Pre-consumer/commercial” is defined as material that is recovered from the waste stream during a manufacturing process. Materials that are reworked or reground, or waste that has been produced in a process, and can be recycled within the same manufacturing process that generated it, are not considered to be pre-consumer recovered material. “Post-consumer/commercial” is defined as material generated by households or commercial, industrial, or institutional facilities in their role as end-users of a product that can no longer be used for its intended purpose. This includes materials from the distribution chain.

Additional information about ingoing substances and impurities:

Limit values: The limit for excluded ingoing substances is 0 ppm (unless otherwise stated), while there's a specific defined limit for impurities. The impurity limit applies separately to each individual excluded substance, from each individual raw material. Concentrations of different impurities with the same excluded classification or substance group characteristics shall not be summed up to meet the impurity limit in the labelled product. Also, concentrations of an individual impurity, originating from different raw materials, shall not be summed.

UVCB substances: UVCB substances (Unknown or Variable composition, Complex reaction products or of biological materials) have a composition of constituents that is not completely known or is variable from time to time. For UVCB substances, all constituents that are known must be declared in the Nordic Swan Ecolabel raw material appendix based on the best available knowledge. All constituents are considered individually and are subject to the chemical requirements, including for instance those on excluded substances and excluded classifications.

4.2 Description of the product and manufacturing process

O1 Description of the product and manufacturing process

The product must be made of min. 90 w% plastic and/or silicone.

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

- Trade name of the product.
- Product category and product type according to the product group definition. Including a description of the product in the form of e.g. a product data sheet or picture of the product.
- Confirmation that product is covered by the Regulation (EU) 2017/745 or EU Medicinal Products Directive (2001/83/EC).
- Total weight of the product (in grams).
- Information whether the product is surface treated and/or if any adhesives are used in the product.
- Information about the different components in the product (like bag for solutions, tubes, connectors etc.) and what specific materials* the different components are made of. The information shall for each component include the following information:
  a) Component of the product/trade name, code/item number corresponding to the flowchart and material type(s).
  b) Supplier of the component including information on production site with full address.
  c) Safety data sheet for each material.
  d) Weight of each material in the component (in grams).
  e) Whether the material(s)* and/or the component has a surface treatment.
- A flowchart showing an overview of the product and the manufacturing process of the product, including information on what components are bought from external

manufacturers and what processes are done externally and internally. An example of a flowchart is shown in Appendix 1.

** Materials can be different plastics such as polypropylene (PP) and polyethylene terephthalate (PET) as well as other kind of materials such as thermoplastic elastomers (TPE), silicone and steel.*

- ☐ Appendix 2 completed and signed by the manufacturer of the product.
- ☐ Description of the product: e.g. product data sheet or picture of the product.
- ☐ Safety data sheets for all materials.
- ☐ Flowchart as described in the requirement.

4.3 Materials in the product

O2 Halogenated plastics

Halogenated plastics, e.g. polyvinyl chloride (PVC), polyvinyl dichloride (PVDC) and polytetrafluoroethylene (PTFE), are not allowed in the product.

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

O3 Halogenated butyl rubber

Halogenated butyl rubbers, e.g., chlorobutyl rubber and bromobutyl rubber, are not allowed in the product.

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

O4 Natural rubber latex

Natural rubber latex is not allowed in the product.

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

O5 Silicone

For silicone and siloxanes used in adhesive or surface treatment (e.g. silicone oil) see requirements in section 4.5.

Silicone material must meet:

- Be medical-grade silicone or tested according to ISO 10993 or USP class VI.
- Octamethylcyclotetrasiloxane, D4, (CAS NO.556-67-2), decamethylcyclopenta-siloxane, D5, (CAS NO.541-02-6) or dodecamethylcyclohexasiloxane, D6, (CAS NO.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 each substance in the silicone material. The number of impurities must be tested according to test method for silicone elastomer products from CES-Silicones Europe[1] or any ISO/IEC 17025-validated GC-MS method achieving LOQs at or below 100 ppm. The

[1] Quantification-of-Residual-Amounts-of-Cyclic-Volatile-Methyl-Siloxanes-in-Silicone-Elastomers_final-002.pdf

analysis laboratory shall fulfil the general requirements of standard EN ISO/IEC 17025 or have official GLP status.

For **small parts** weighing a maximum of 2 grams and that are not introduced** into the patient during treatment, the following applies:

- Octamethylcyclotetrasiloxane, D4, (CAS NO.556-67-2), decamethylcyclopenta-siloxane, D5, (CAS NO.541-02-6) or dodecamethylcyclohexasiloxane, D6, (CAS NO.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 for each substance in the silicone material. This must be declared by the manufacturer/supplier of the silicone (appendix 3).

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

*** By introduced means parts that penetrated the skin or are placed inside the body.*

- ☐ Appendix 3 or equivalent, completed and signed by the manufacturer/supplier of the silicone.
- ☐ Test report showing the amount of D4, D5 and D6 in the silicone material according to test method for silicone elastomer products from CES-Silicones Europe or any ISO/IEC 17025-validated GC-MS method achieving LOQs at or below 100 ppm.
- ☐ Documentation for that the analysis laboratory fulfils the general requirements of standard EN ISO/IEC 17025 or have official GLP status.

4.3.1 Silicone production

Requirements in this section only applies to products made of min. 80 w% silicone.

O6 Emissions of dust and chlorides to air

1. Emissions of dust

1a) The manufacturer of the silicone shall for storage and handling of the elemental silicon raw material use at least one of the following techniques:

- Storing of elemental silicon in silos (after grinding).
- Storing of elemental silicon in covered areas protected from rain and wind (after grinding).
- Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage (after grinding).
- Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.

1b) The yearly average of channelled emissions of dust shall be below 5 mg/Nm^3. The dust emissions should be continuously monitored.

Methods accepted are EN 15267-1, EN 15267-2, EN 15267-3, EN 15267-4, EN 13284-1 and EN 13284-2. The measurement shall cover grinding, storage and handling of elemental silicon as a minimum.

2. Emissions of chlorides

The off gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. Burning of chlorinated compounds shall be authorised in the thermal oxidation process.

- Appendix 4 completed and signed by the manufacturer of the silicone.
- Test reports with results of the dust measurements taken on site, together with calculation for the yearly average of the dust emission, see Appendix 4.
- Details on the processing of the off gases from the methyl chloride, direct synthesis and distillation steps, see Appendix 4.

O7 Emissions of copper and zinc to water

The water effluents from the polydimethylsiloxane (PDMS) production step shall be pre-treated by precipitation or flocculation under alkaline conditions, followed by sedimentation and filtration. This shall include:

a) dewatering of the sludge before disposal; and

b) recovering of the solid metal residues in metal recovery plants.

The concentration of copper in the treated effluent shall be below 0.5 mg/l, while the concentration of zinc shall be below 2 mg/l. However, if national or local legislation is stricter, then these levels must be met.

- Appendix 4 completed and signed by the manufacturer of the silicone.
- Results for copper and zinc measurements in the treated effluent and test reports for these, see Appendix 4.

O8 Energy consumption for silicone

Energy consumption data for each energy source must be reported for the production site* of the silicone.

** From gate to gate (phase A3 in EPDs) in all factories (manufacturing, packaging, etc.) manufacturing silicone for Nordic Swan Ecolabelled products. All energy use shall be reported (production, heating of buildings etc.) regardless of the proportion that is dedicated to manufacturing silicone for Nordic Swan Ecolabel products. Internal logistics (e.g. forklifts) and facility operations (e.g. canteens) are included. Upstream/downstream processes (e.g. distribution to retailers) are excluded.*

- Completed reporting sheet (available on Nordic Ecolabelling's websites).
- Documentation confirming purchased/generated energy from the last 12 months (e.g. invoices or similar documents).
- Appendix 4 completed and signed by the manufacturer of the silicone.

4.4 Additives in polymer materials

This section covers requirements to additives, e.g., plasticisers, colourants/pigments and antioxidants, added to the masterbatch or compound. The requirement does not include the polymer production itself. Polymer materials are e.g. plastics (e.g. PP, PET), thermoplastic elastomers (TPE), silicone, synthetic latex and other rubbers.

The requirements in this section and accompanying appendices apply to all ingoing substances in the additives. Impurities are not regarded as ingoing substances and are

exempt from the requirements. Ingoing substances and impurities are defined in section 4.1 Definitions, unless stated otherwise in the requirements.

Polymer materials used in adhesive or surface treatment are not covered by this section but are covered by section 4.5.

O9 Classification of ingoing substances in additives

Ingoing substances* in the additives used in the materials must not be classified with any of the hazards from CLP Regulation (EC) No 1272/2008 listed below.

** See definition in section 4.1.*

Table 1 Excluded hazards

Hazard Class	Hazard Category	Hazard Statement Code
Hazardous to the ozone layer	Ozone	H420
Specific target organ toxicity: Single or repeated exposure	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Carcinogenicity*	Carc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity*	Muta. 1A or 1B Muta. 2	H340 H341
Reproductive toxicity*	Repr. 1A or 1B Repr. 2 Lact.	H360 H361 H362
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317
Endocrine disruption for human health*	ED HH 1 ED HH 2	EUH380 EUH381
Endocrine disruption for the environment*	ED ENV 1 ED ENV 2	EUH430 EUH431
Persistent, Bioaccumulative and Toxic properties** Very Persistent, Very Bioaccumulative properties**	PBT vPvB	EUH440 EUH441
Persistent, Mobile and Toxic properties Very Persistent, Very Mobile properties	PMT vPvM	EUH450 EUH451

** Includes all classification variants (e.g. H350 also covers H350i).*

*** See also requirement O10 Excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances.*

Exemption applies to:

- When required for regulatory reasons to avoid release of n-nitrosamine from polyisoprene parts, exemption is given to antioxidants classified as toxic to reproduction cat 2 (H361) as additive in the part at maximum 0.5% and assessed as safe and not detectable in an ISO 10993 evaluation.

☐ Appendix 5 completed and signed by the manufacturer/supplier of the polymer material.

☐ Exemption for antioxidants classified as H361 in polyisoprene parts:

- Data from licensee confirming that a replacement is required for regulatory reasons due to release of n-nitrosamine impurities from polyisoprene part(s).
- Data from supplier showing that the level of such antioxidant does not exceed 0.5% in the polyisoprene material.
- An evaluation according to ISO 10993 concluding that the use of an antioxidant (classified as above) in the polyisoprene part is safe, and that the antioxidant is not released in detectable amounts from the medicinal product and medical device.

O10 Excluded substances in additives

The following substances or substance groups must not be present as ingoing substances* in the additives used in the materials.

** See definition in section 4.1.*

- Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate-list-table

  For D4, D5 and D6 in silicone polymers, see O5.
- PBT and vPvB as defined in REACH Annex XIII, including those under ECHA PBT assessment https://echa.europa.eu/da/pbt
- Potential or identified endocrine disruptors, listed in any of the following "Endocrine Disruptor Lists" List I; II and III

  Note: Substances moved to "Substances no longer on list" and not present on Lists I-III, are no longer excluded, except for those on sublist II where concern remains. Nordic Ecolabelling will assess these on a case-by-case basis.
- Phthalates (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid))
- Azo dyes that may release aromatic amines with carcinogenic, reproductive toxicity or mutagenic properties listed in Regulation (EC) No 1907/2006, Annex XVII, Appendix 8
- Bisphenols and bisphenol derivatives, defined as 34 bisphenols identified by ECHA[2] for further EU regulatory risk management due to known or potential endocrine disruption or reproductive toxicity
- Per- and polyfluoroalkyl substances (PFAS)

  Defined as any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).
- Halogenated organic compounds
- Metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As) and antimony (Sb).

[2] EC/List No. 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5 (BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS, 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA).
[1] Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed https://echa.europa.eu/documents/10162/5e60f2fe-12d0-7f6b-5868-f199cfd7f984

- Appendix 5 completed and signed by the manufacturer/supplier of the polymer material.

4.5 Adhesive and surface treatment

This section covers requirements to adhesives and surface treatments used in or on the products and the various parts/components of the product. There are no requirements for chemicals used for maintenance of machines or in the production processes (such as lubricants, cleaning chemicals etc.).

The requirements in this section do not apply to adhesive or surface treatment used for packaging unless the packaging is part of the product.

The requirements in this section and accompanying appendices apply to all ingoing substances in the adhesives and surface treatments. Impurities are not regarded as ingoing substances and are exempt from the requirements. Ingoing substances and impurities are defined in section 4.1 Definitions, unless stated otherwise in the requirements.

O11 Classification of adhesive and surface treatment

Adhesives and surface treatments used in or on the product and the various parts/components of the product must not be classified with any of the hazards from CLP Regulation (EC) No 1272/2008 listed below.

Table 2 Excluded hazards

Hazard Class	Hazard Category	Hazard Statement 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
Hazardous to the ozone layer	Ozone	H420
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: Single or repeated exposure	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317
Carcinogenicity*	Carc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity*	Muta. 1A or 1B Muta. 2	H340 H341

Reproductive toxicity*	Repr. 1A or 1B Repr. 2 Lact.	H360 H361 H362
Endocrine disruption for human health	ED HH 1 ED HH 2	EUH380 EUH381
Endocrine disruption for the environment	ED ENV 1 ED ENV 2	EUH430 EUH431
Persistent, bioaccumulative and toxic properties Very persistent, very bioaccumulative properties	PBT vPvB	EUH440 EUH441
Persistent, Mobile and Toxic properties Very Persistent, Very Mobile properties	PMT vPvM	EUH450 EUH451

** Includes all classification variants (e.g. H350 also covers H350i).*

Exemptions apply to:

- UV-cured acrylates-based adhesives cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.
- The classification H317 is exempted for the hardener in 2-component adhesives that do not come into contact with the medicinal solution or the patient during treatment.

- A safety data sheet (SDS) for the adhesive and surface treatment, prepared in accordance with Annex II of REACH Regulation (EC) No 1907/2006.
- Appendix 6 completed and signed by the manufacturer/supplier of the adhesive or surface treatment.
- Exemption for UV-cured acrylates-based adhesives: Description of the application system and how workers are protected from exposure.
- Exemption for hardener in 2-component adhesives: Declaration of the application that the adhesive does not come into contact with the medicinal solution or the patient during treatment.

O12 Classification of ingoing substances in adhesive and surface treatment

Ingoing substances* in the adhesives and surface treatments used in or on the product and the various parts/components of the product must not be classified with any of the hazards from CLP Regulation (EC) No 1272/2008 listed below.

** See definition in section 4.1.*

Table 3 Excluded hazards

Hazard Class	Hazard Category	Hazard Statement Code
Hazardous to the ozone layer	Ozone	H420
Specific target organ toxicity: Repeated exposure	STOT RE 1	H372
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317
Carcinogenicity*	Carc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity*	Muta. 1A or 1B Muta. 2	H340 H341

Reproductive toxicity*	Repr. 1A or 1B Repr. 2 Lact.	H360 H361 H362
Endocrine disruption for human health**	ED HH 1 ED HH 2	EUH380 EUH381
Endocrine disruption for the environment**	ED ENV 1 ED ENV 2	EUH430 EUH431
Persistent, Bioaccumulative and Toxic properties** Very Persistent, Very Bioaccumulative properties**	PBT vPvB	EUH440 EUH441
Persistent, Mobile and Toxic properties Very Persistent, Very Mobile properties	PMT vPvM	EUH450 EUH451

** Includes all classification variants (e.g. H350 also covers H350i).*

*** See also requirement O13 Excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances.*

Exemptions apply to:

- The classifications H317 and H334 are exempted for the hardener in 2-component adhesives that do not come into contact with the medicinal solution or the patient during treatment.
- Exemption 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.
- Exemption is given to photoinitiators in UV-cured acrylates-based adhesives and in UV-cured surface treatment, if the chemical product is cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.
- The classification H317 is exempted if used in UV-cured acrylates-based adhesives cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.

t Appendix 6 completed and signed by the manufacturer/supplier of the adhesive or surface treatment.

t Exemption for 2-component adhesives with isocyanates (classified H351), a description of how the workers are protected and how the legislation for working environment is fulfilled.

t Exemption for photoiniators in UV-cured acrylates-based adhesives and UV-cured surface treatment: Description of the application system and how workers are protected from exposure.

t Exemption for H317 in UV-cured acrylates-based adhesives: Description of the application system and how workers are protected from exposure.

O13 Excluded substances in adhesive and surface treatment

The following substances or substance groups must not be present as ingoing substances* in adhesives or surface treatment chemicals.

** See definition in section 4.1.*

- Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate-list-table

  For D4, D5 and D6 in silicone polymers, see O14.

- PBT and vPvB as defined in REACH Annex XIII, including those under ECHA PBT assessment https://echa.europa.eu/da/pbt
- Potential or identified endocrine disruptors, listed in any of the following "Endocrine Disruptor Lists" List I; II and III

  Note: Substances moved to "Substances no longer on list" and not present on Lists I-III, are no longer excluded, except for those on sublist II where concern remains. Nordic Ecolabelling will assess these on a case-by-case basis.
- Phthalates (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid))
- Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS NO. 25013-16-5), butylated hydroxytoluene (BHT, CAS NO. 128-37-0), alkylphenol ethoxylates (APEOs) and other alkylphenol derivates (APD)
- Per- and polyfluoroalkyl substances (PFAS)

  Defined as any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).
- Halogenated organic compounds
- Metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As) and antimony (Sb)
- Bisphenols and bisphenol derivatives, defined as 34 bisphenols identified by ECHA[3] for further EU regulatory risk management due to known or potential endocrine disruption or reproductive toxicity
- Quaternary ammonium compounds, which are not readily aerobic biodegradable* such as DTDMAC (CAS NO. 61789-80-8), DSDMAC (CAS NO. 107-64-2), DHTDMAC (CAS NO. 61789-72-8) and DADMAC (CAS NO. 7398-69-8)

  ** According to OECD test method 301 (A-F) or 310 or equivalent methods evaluated by an independent body and controlled by Nordic Ecolabelling.*
- Volatile aromatic compounds (VAC) (volatile organic compounds containing one or more benzene rings)
- Nanomaterials/-particles

  Nanomaterials/-particles are defined according to the EU Commission Recommendation on the Definition of Nanomaterial (2022/C 229/01)10:
  'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50% or more of these particles in the number-based size distribution fulfil at least one of the following conditions:
  (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm;
  (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;

[3] EC/List No. 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5 (BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS, 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA).
[1] Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed https://echa.europa.eu/documents/10162/5e60f2fe-12d0-7f6b-5868-f199cfd7f984

(c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.

- ☐ Appendix 6 completed and signed by the manufacturer/supplier of the adhesive or surface treatment.

O14 Silicone in adhesive and surface treatment

This requirement applies to silicone and siloxanes used in adhesive or surface treatment, e.g. silicone oil.

Octamethylcyclotetrasiloxane, D4, (CAS NO.556-67-2), decamethylcyclopenta-siloxane, D5, (CAS NO.541-02-6) and dodecamethylcyclohexasiloxane, D6, (CAS NO.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 each substance. The impurities must be tested according to test method for silicone fluids from CES-Silicones Europe[4] or any ISO/IEC 17025-validated GC-MS method achieving LOQs at or below 100 ppm. The analysis laboratory shall fulfil the general requirements of standard EN ISO/IEC 17025 or have official GLP status.

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

- ☐ Appendix 6 or equivalent, completed and signed by the manufacturer/supplier of the adhesive or surface treatment.
- ☐ Test report showing the amount of D4, D5 and D6 in the silicone material according to test method for silicone fluids from CES-Silicones Europe or any ISO/IEC 17025-validated GC-MS method achieving LOQs at or below 100 ppm.
- ☐ Documentation for that the analysis laboratory fulfils the general requirements of standard EN ISO/IEC 17025 or have official GLP status.

4.6 Energy

O15 Energy management

The manufacturing sites that perform sterilization of the final product must actively work with energy savings by either:

- Being certified according to ISO 50001 or
- Being certified according to ISO 14001 (must contain an energy review corresponding to part 6.3 of ISO 50001 upon recertification) or
- Have undergone an audit according to EN 16247 within the last four years or
- Have undergone an energy audit within the last four years according to the national implementation of the Energy Efficiency Directive (2012/27/EU, article 8).

Furthermore, an action plan resulting from the energy mapping/audit and with purpose to reduce energy consumption must be developed.

If a new energy audit and a new energy mapping must be conducted again during the validity of the criteria, new action plans or other up-to-date documents must be handed in to

[4] Quantification-of-residual-amounts-of-Volatile-Siloxanes-in-silicone-products_final.pdf

Nordic Ecolabelling. It is the license holder's responsibility to make and maintain follow-up plans so that this requirement is always fulfilled.

- Documentation for certification according to ISO 50001, ISO 14001 (including extended energy review corresponding to part 6.3 of ISO 50001 upon recertification) or audit according to EN 16247 within the last four years or audit according to a national implementation of the Energy Efficiency Directive (2012/27/EU, article 8) within the last four years.
- Action plan for reducing energy consumption.

4.7 Packaging

O16 Packaging materials

The requirement applies to primary, secondary and tertiary packaging* unless otherwise stated.

Small parts such as stables, plastic strips, closure clips and cords are exempt from the requirement.

Description of the packaging:

Description of all the materials (including type of polymer e.g. PP) in the primary, secondary and tertiary packaging including container, lid and label, respectively.

Plastic:

Halogenated plastics (e.g. polyvinyl chloride (PVC) and polyvinylidene chloride (PVDC)), oxo-degradable plastic and biodegradable plastic must not be used in the packaging or labels.

Board and paper:

A minimum of 70 w% of the wood raw material in the paper- and board packaging must be recycled* or must come from forests that are managed in accordance with sustainable forestry management principles established by FSC- or PEFC-schemes**.

The remaining proportion of wood raw material must be covered by the FSC/PEFC control schemes (FSC controlled wood/PEFC controlled sources).

The paper part of protective blister in primary packaging is exempt.

Metal:

Metals must not be used.

For primary packaging is exception of metal layer for barrier purposes to preserve a sterile barrier, minimize evaporation and/or improve product shelf life.

** See definition in section 4.1.*

*** Purchased board and paper are either a) On-product labelled as FSC 100%/-mix/-recycled or PEFC certified/recycled or b) documented with invoices/delivery notes which confirms FSC/PEFC claims according to sustainable forest management principles issued by FSC or PEFC. In case of suppliers with different claims the annual calculation must be ≥70%.*

- Description of all the materials in the primary, secondary and tertiary packaging container, lid and label respectively. Appendix 7 completed and signed by the applicant.

- Appendix 8 completed and signed by the packaging manufacturer/supplier.
- For board and paper: Documentation showing that the quantity of certified wood raw material or recycled material is met, and the remaining proportion is covered by FSC/PEFC's control schemes (FSC controlled wood/PEFC controlled sources). This shall be specified in e.g. invoices or delivery notes from suppliers. The requirement must be documented as purchased amount annually.

O17 Packaging design for recycling

Requirement for primary packaging*:

Must not contain intentionally added PFAS**, nor be surface treated with PFAS, either on the inside or on the outside of the packaging.

Requirements for secondary packaging and tertiary packaging*:

The packaging must fulfil that:

- All components* that are comprised of different materials (including different plastic types) must be possible to be sorted separately for recycling** without using a tool.

  Mixed materials that cannot be separated must not be used. Different materials must not be glued or welded together.
- Must not contain intentionally added PFAS***, nor be surface treated with PFAS, either on the inside or on the outside of the packaging.
- In addition, for plastic packaging: Carbon black pigments must not be added to plastic materials.

** See definition in section 4.1.*

*** Energy recovery does not qualify as recycling.*

**** PFAS: as any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).*

For primary packaging:

- Declaration that the packaging has not been added nor treated with PFAS. Appendix 7 completed and signed by the applicant and Appendix 8 completed and signed by the packaging manufacturer/supplier.

For secondary packaging and tertiary packaging:

- Picture/artwork of packaging and description of how the packaging's components of different materials can be separated without using tools.
- Appendix 7 completed and signed by the applicant.
- Appendix 8 completed and signed by the packaging manufacturer/supplier.

4.8 Safety

O18 Safety

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

For medical devices the CE marking shall be visible on the label.

The manufacturing site of the final product must be certified according to ISO 13485 or EN ISO 13485 “Medical devices – Quality management systems – Requirements for regulatory purposes”.

- 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.
- Medical device: The label showing CE marking.
- Copy of certificate for ISO 13485 or EN ISO 13485.

4.9 Licence maintenance

The purpose of the licence maintenance is to ensure that fundamental quality assurance is dealt with appropriately.

O19 Customer complaints

The licensee must guarantee that the quality of the Nordic Swan Ecolabel product or service does not deteriorate during the validity period of the licence. Therefore, the licensee must keep an archive over customer complaints.

Note that the original routine must be in one Nordic language or in English.

- Upload your company’s routine for handling and archiving customer complaints.

O20 Traceability

The licensee must be able to trace the Nordic Swan Ecolabel products in the production. A manufactured / sold product should be able to trace back to the occasion (time and date) and the location (specific factory) and, in relevant cases, also which machine/production line where it was produced. In addition, it should be possible to connect the product with the actual raw material used.

You can upload your company’s routine or a description of the actions to ensure traceability in your company.

- Please upload your routine or a description.

5 Criteria version history

Nordic Ecolabelling adopted version 3.0 of the criteria for Nordic Swan Ecolabel Medical devices and medicinal products in plastic and silicone on 1 June 2026. The criteria are valid until 31 August 2031.

6 How to apply and regulations for the Nordic Ecolabelling

Application and costs

For information about the application process and fees for this product group, please refer to the respective national website. For contact information see the beginning of this document.

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

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 prolonged or adjusted, in which case the licence is automatically prolonged, 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.

Responsibility for Compliance with Applicable Legislation

When applying for the Nordic Swan Ecolabel, the applicant/licensee confirms compliance with all current regulatory requirements related to both the exterior and interior environment in connection with the production and handling of the product(s) covered by the application. Furthermore, the applicant declares that all applicable regulatory requirements within the Nordic region are met for the product(s). Compliance with these regulations is a prerequisite for obtaining a licence.

On-site inspection

In connection with handling of the application, Nordic Ecolabelling normally performs on-site inspection visit/-s 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 contact info in the beginning of this document. Further information and assistance (such as calculation sheets or electronic application help) is available. Visit the relevant national website for further information.

Follow-up inspections

Nordic Ecolabelling may decide to check whether the medical device 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 medical device does not meet the requirements.

Random samples may also be taken in-store and analysed by an independent laboratory. If the requirements are not met, Nordic Ecolabelling may charge the analysis costs to the licensee.

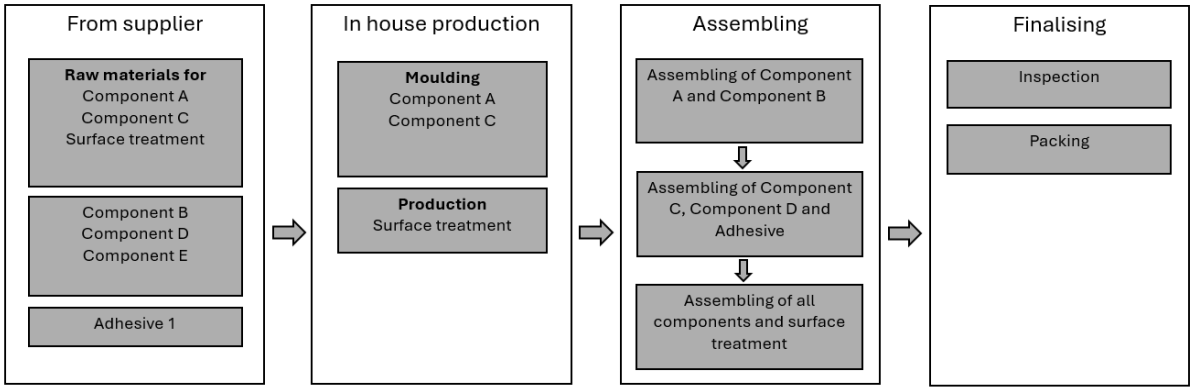
Regulations for the Nordic Ecolabelling of products

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-swan-ecolabel.org/regulations

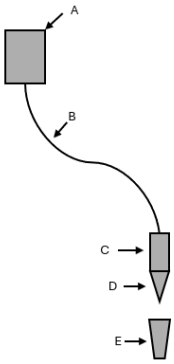
Appendix 1 Flowchart - Manufacturing process for the product

Example of flowchart:



Picture/drawing of the product

Overview of components and materials in the product



Component	Component of the product	Material	Supplier
Component A			
Component B			
Component C			
Component D			
Component E			
-	Adhesive		
-	Surface treatment		

Appendix 2 Manufacturers description of the product

General information of the product

O1 Description of the product and manufacturing process		
Trade name of the product:	Name:	
Product category (see product group definition):	Masks	
	Flexible tubes	
	Bags	
	Plugs	
	Syringes	
	Tubes	
Type of product (e.g. anaesthesia mask, tracheal tube, drainage bag):	Type:	

	YES	**NO**
Is the product in accordance with the EU Medical Devices Regulation (2017/745)?		
Is the product in accordance with the EU Medicinal Products Directive (2001/83/EC)?		
Is the product surface treated?		
Are any adhesives used in the product?		

Total weight of the product* (g): * Excluding weight of fluids in dialysis bags and prefilled syringes	Weight:

O2 Halogenated plastics	**YES**	**NO**
Does the product contain any halogenated plastics?		
O3 Halogenated butyl rubber		
Does the product contain any halogenated butyl rubber?		
O4 Natural rubber latex		
Does the product contain any natural rubber latex?		

O11 Classification of adhesive and surface treatment **O12 Classifications of ingoing substances in adhesive and surface treatment** **(according to CLP regulation 1272/2008)**		
If applicable in your internal process for UV-cured acrylates-based adhesives with any classifications in O11: Is the UV-cured acrylates-based adhesives cured in a closed production system where there is no direct contact/exposure between worker and the chemical product?		
If applicable in your internal process for UV-cured acrylates-based adhesives or UV-cured surface treatment with photoinitiators with any classifications in O12: Is the chemical product cured in a closed production system where there is no direct contact/exposure between worker and the chemical product?		
If applicable in your internal process for UV-cured acrylates-based adhesives with ingoing substances classified H317: Is the chemical product cured in a closed production system where there is no direct contact/exposure between worker and the chemical product?		
If applicable in your internal process for hardener in 2-component adhesives classified H317 and/or H334: Does the 2-component adhesive come into contact with the medicinal solution or the patient during treatment?		
If applicable in your internal process for 2-component adhesives with isocyanates classification H351: Are the workers exposed during the production of the product?		
Are the isocyanates are cured in the finished product?		
Is legislation for working environment fulfilled?		

Components of the product

In the table below, add information about the different components of the finished product. Each component should correspond to a component in the flowchart.

Component code (from flow-chart)	**Component of the product/trade name**	**Material type (e.g. PP, TPE, silicone)**	**Is the component produced internally or externally?**	**Is the component surface treated?**	**Name of manufacturer/supplier of the component and their address**	**Weight of each material in the component (g)**

Additives in the plastic

In the table below, add information about all additives (e.g. plasticisers, colourants/pigments, antioxidants) included in the product.

Component code (from flow-chart)	Component of the product/trade name	Additives (chemical name and/or CAS No)	Function

In the event of any changes of the information in this declaration, a new declaration must be submitted to Nordic Ecolabelling.

Signature of the manufacturer of the product:

Place and date	Company name
Responsible person	Signature of responsible person
Telephone	Email

Appendix 3 Declaration from the manufacturer of silicone

Manufacturer/supplier:
Trade name of the silicone material:

D4: Octamethylcyclotetrasiloxane, (CAS NO.556-67-2)

D5: Decamethylcyclopenta-siloxane, (CAS NO.541-02-6)

D6: Dodecamethylcyclohexasiloxane, (CAS NO.540-97-6)

	YES	NO
Is the silicone medical-grade silicone? *Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.*		
Is the silicone tested according to ISO 10993? *Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.*		
Is the silicone tested according to USP class VI? *Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.*		
Do D4, D5 or D6 form part of the silicone material?		
Please state amount of impurities* of D4, D5 and D6 in the silicone material: D4: _____ ppm D5: _____ ppm D6: _____ 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.*		
Is test report showing the amount of D4, D5 and D6 in the silicone material according to test method for silicone elastomer products from CES-Silicones Europe* or any ISO/IEC 17025-validated GC-MS method achieving LOQs at or below 100 ppm attached? * Quantification-of-Residual-Amounts-of-Cyclic-Volatile-Methyl-Siloxanes-in-Silicone-Elastomers_final-002.pdf *Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.*		
Is documentation for the analysis laboratory fulfils the general requirements of standard EN ISO/IEC 17025 or have official GLP status attached? *Please note: Not required for small silicone parts (max 2 gram) that are not introduced into the patient during treatment. By introduced means parts that penetrated the skin or are placed inside the body.*		

Place and date	Company name
Responsible person	Signature of responsible person
Telephone	Email

Appendix 4 Declaration from the manufacturer of silicone about production of silicone

To be submitted with an application for a Nordic Swan Ecolabel licence.

Please note that for silicone Appendix 3 and Appendix 5 must also be completed.

Manufacturer:
Trade name of the silicone material:

Production of silicone

O6 Emission of dust and chlorides **The storage and handling of the elemental silicon raw material shall use at least one of the following techniques, see below, please specify which techniques are used.**	**YES**	**NO**
Storing of elemental silicon in silos (after grinding)		
Storing of elemental silicon in covered areas protected from rain and wind (after grinding)		
Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage (after grinding)		
Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.		
The yearly average of channelled emissions of dust shall be below 5 mg/Nm^3. The dust emissions should be continuously monitored. Attach test results of the dust measurements taken on site, together with the yearly average of the dust emission. Methods accepted are EN 15267-1, EN 15267-2, EN 15267-3, EN 15267-4, EN 13284-1 and EN 13284-2. The measurement shall cover grinding, storage and handling of elemental silicon as a minimum. Name of attachment: _____		
Is the yearly channelled dust emission on average below 5 mg/Nm^3?		
The off gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. Burning of chlorinated compounds shall be authorised in the thermal oxidation process. Attach details on the processing of the off gases from the methyl chloride, direct synthesis and distillation steps. Name of attachment: _____		

O7 Emissions of copper and zinc to water	**YES**	**NO**
Are the water effluents from the polydimethylsiloxane (PDMS) production step pre-treated by precipitation or flocculation under alkaline conditions, followed by sedimentation and filtration? Including dewatering of the sludge before disposal and recovering of the solid metal residues in metal recovery plants? **Attach** description how the effluent is treated. Name of attachment:_____		

Is the concentration of zinc in the treated effluent below 2 mg/l? Attach test report for zinc measurements. Name of attachment: _____		
Is the concentration of copper in the treated effluent below 0.5 mg/l? Attach test report for copper measurements. Name of attachment: _____		
O8 Energy consumption		
Energy consumption data for each energy source must be reported for the production site* of the silicone. Attach completed reporting sheet (available on Nordic Ecolabelling's websites) for the last 12 months, name of attachment: _____ Documentation confirming purchased/generated energy from the last 12 months (e.g. invoices or similar documents), name of attachment: _____ ** From gate to gate (phase A3 in EPDs) in all factories (manufacturing, packaging, etc.) manufacturing silicone for Nordic Swan Ecolabelled products. All energy use shall be reported (production, heating of buildings etc.) regardless of the proportion that is dedicated to manufacturing silicone for Nordic Swan Ecolabel products. Internal logistics (e.g. forklifts) and facility operations (e.g. canteens) are included. Upstream/downstream processes (e.g. distribution to retailers) are excluded.*		

Place and date	**Company name**
Responsible person	**Signature of responsible person**
Telephone	**Email**

Appendix 5 Declaration of additive used in plastic, silicone or rubber

Filled out by:

Manufacturer/supplier of additive:	
Manufacturer/supplier of plastic, silicone or rubber:	

To be submitted with an application for a Nordic Swan Ecolabel licence.

This declaration is based on the best available knowledge at the time of the application, including test results. If new information or scientific findings become available, please inform Nordic Ecolabelling and submit an updated declaration.

For suppliers: If you do not have knowledge about the complete composition of the additives in the polymer material, you are obliged to obtain this information from the manufacturer.

Manufacturer/supplier:
(When declaration is filled out by manufacturer/supplier of additive) **Trade name of the additive:**
(When declaration is filled out by manufacturer/supplier of additive) **Type of additive (e.g. plasticisers, colourants/pigments, antioxidants):**
(When declaration is filled out by manufacturer/supplier of plastic, silicone or rubber) **Trade name of the polymer material:**
(When declaration is filled out by manufacturer/supplier of plastic, silicone or rubber) **Type of polymer material (e.g. PP, PET, TPE, silicone):**

This appendix covers requirements to additives, e.g., plasticisers, colourants/pigments and antioxidants, added to the masterbatch or compound. The requirement does not include the polymer production itself.

The requirements in this section and accompanying appendices apply to **all ingoing substances in the additives**. Impurities are not regarded as ingoing substances and are exempt from the requirements. Ingoing substances and impurities are defined as below, unless stated otherwise in the requirements.

Ingoing substances: All substances* in the chemical product/additive regardless of amount, including additives (e.g., preservatives and stabilizers) in the raw materials. Substances released from ingoing substances (e.g., biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances.

** N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance (Unknown or Variable composition, Complex reaction products or of biological materials) are also regarded separately, and all known constituents must be regarded.*

Impurities: Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials, that remain in the chemical product or additive in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%).

Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the chemical product or additive.

Examples of impurities: Background environmental pollutants from feedstock, as well as contaminants and residues from production such as reactants (incl. monomers), reagents, catalysts, by-products, scavengers, detergents for production equipment, carry-over from other or previous production lines.

Additional information concerning definitions of ingoing substances and impurities:

Limit values: The limit for excluded ingoing substances is 0 ppm (unless otherwise stated), while there's a specific defined limit for impurities. The impurity limit applies separately to each individual excluded substance, from each individual raw material. Concentrations of different impurities with the same excluded classification or substance group characteristics shall not be summed up to meet the impurity limit in the labelled product. Also, concentrations of an individual impurity, originating from different raw materials, shall not be summed.

UVCB substances: UVCB substances (Unknown or Variable composition, Complex reaction products or of biological materials) have a composition of constituents that is not completely known or is variable from time to time. For substances registered under REACH as UVCBs, all constituents are considered individually and are subject to the chemical requirements, including for instance those on excluded substances and excluded classifications.

If **the additives** contain ingoing substances or impurities that are listed under excluded substances or has any of the classifications mentioned in this appendix, write the amount in the box at the end of the appendix.

O9 Classifications of ingoing substances in additives (according to CLP regulation 1272/2008)		
Do the additives contain ingoing substances or impurities classified with any of the hazard codes below? Including all classification variants (e.g. H350 also includes H350i).	**YES**	**NO**
H420 – Ozone		
H370 – STOT SE 1		
H371 – STOT SE 2		
H372 – STOT RE 1		

H373 – STOT RE 2		
H350 – Carc. 1A or 1B		
H351 – Carc. 2		
H340 – Muta. 1A or 1B		
H341 – Muta. 2		
H360 – Repr. 1A or 1B		
H361 – Repr 2 ***If yes** because of polyisoprene parts with H361, the following documentation must be attached:* *• Data from licensee confirming that a replacement is required for regulatory reasons due to release of n-nitrosamine impurities from polyisoprene part(s).* *• Data from supplier showing that the level of such antioxidant does not exceed 0.5% in the polyisoprene material.* *• An evaluation according to ISO 10993 concluding that the use of an antioxidant (classified as above) in the polyisoprene part is safe, and that the antioxidant is not released in detectable amounts from the medicinal product and medical device.*		
H362 – Lact.		
H334 – Resp. Sens. 1, 1A or 1B		
H317 – Skin Sens. 1, 1A or 1B		
EUH380 – ED HH 1		
EUH381 – ED HH 2		
EUH430 – ED ENV 1		
EUH431 – ED ENV 2		
EUH440 – PBT		
EUH441 – vPvB		
EUH450 – PMT		
EUH451 – vPvM		
O10 Excluded substances in additives		
Do the additives contain any of the following as ingoing substances or impurities?	**Yes**	**No**
Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate-list-table *For D4, D5 and D6 in silicone polymers, use Appendix 3.*		
PBT and vPvB as defined in REACH Annex XIII, including those under ECHA PBT assessment https://echa.europa.eu/da/pbt		
Potential or identified endocrine disruptors, listed in any of the following "Endocrine Disruptor Lists" List I; II and III		

Phthalates (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid))		
Azo dyes that may release aromatic amines with carcinogenic, reproductive toxicity or mutagenic properties listed in Regulation (EC) No 1907/2006, Annex XVII, Appendix 8		
Bisphenols and bisphenol derivatives, defined as 34 bisphenols identified by ECHA for further EU regulatory risk management due to known or potential endocrine disruption or reproductive toxicity. *EC/List No. 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5 (BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS, 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA)*		
Per- and polyfluoroalkyl substances (PFAS) *PFAS is defined as any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it)*		
Halogenated organic compounds *Exemption for: Pigments that meet the EU's requirement concerning colourants in food packaging under Resolution AP (89) point 2.5.* *Please note: Per- and polyfluoroalkyl substances (PFAS) are covered by their own bullet and are not included in the exemption.*		
Metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)		

If the answer to any of the above questions regarding ingoing substances or impurities is Yes, please provide the following information for each relevant substance: CAS NO. (where possible), chemical name, concentration (in ppm, % by weight or mg/kg). Also state whether the substance is present as an ingoing substance or impurity.

If the additives composition change, a new declaration confirming compliance with the requirements must be submitted to Nordic Ecolabelling.

Place and date	**Company name**
Responsible person	**Signature of responsible person**
Telephone	**Email**

Appendix 6 Declaration from the manufacturer/supplier of adhesive or surface treatment

To be submitted with an application for a Nordic Swan Ecolabel licence.

This declaration is based on the best available knowledge at the time of the application, including test results. If new information or scientific findings become available, please inform Nordic Ecolabelling and submit an updated declaration.

For suppliers: If you do not have knowledge about the complete composition of the raw material/ingredient, you are obliged to obtain this information from the manufacturer.

Manufacturer/supplier:
Trade name of the adhesive or surface treatment:

The requirements in the criteria document and accompanying appendices apply to all ingoing substances in the adhesive or surface treatment. Impurities are not regarded as ingoing substances and are exempt from the requirements. Ingoing substances and impurities are defined as below, unless stated otherwise in the requirements.

Ingoing substances: All substances* in the adhesive or surface treatment regardless of amount in the raw materials. Substances released from ingoing substances (e.g., biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances.

** N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance (Unknown or Variable composition, Complex reaction products or of biological materials) are also regarded separately, and all known constituents must be regarded.*

Impurities: Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials, that remain in the chemical product or additive in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%).

Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the chemical product or additive.

Examples of impurities: Background environmental pollutants from feedstock, as well as contaminants and residues from production such as reactants (incl. monomers), reagents, catalysts, by-products, scavengers, detergents for production equipment, carry-over from other or previous production lines.

Additional information concerning definitions of ingoing substances and impurities:

Limit values: The limit for excluded ingoing substances is 0 ppm (unless otherwise stated), while there's a specific defined limit for impurities. The impurity limit applies separately to each individual excluded substance, from each individual raw material. Concentrations of different impurities with the same excluded classification or substance group characteristics shall not be summed up to meet the impurity limit in the labelled product. Also, concentrations of an individual impurity, originating from different raw materials, shall not be summed.

UVCB substances: UVCB substances (Unknown or Variable composition, Complex reaction products or of biological materials) have a composition of constituents that is not completely known or is variable from time to time. For substances registered under REACH as UVCBs, all constituents are considered individually and are subject to the chemical requirements, including for instance those on excluded substances and excluded classifications.

If the adhesive or surface treatment contain ingoing substances or impurities that are listed under excluded substances or has any of the classifications mentioned in this appendix, write the amount in the box at the end of the appendix. The manufacturer of the Nordic Swan Ecolabelled product is responsible for calculating compliance with the requirements of the criteria.

Type of adhesive/surface treatment	**YES**	**NO**
UV-cured acrylates-based adhesive		
UV-cured surface treatment		
2-component adhesive		
Other: (please state)		

O11 Classifications of the adhesive or surface treatment (according to CLP regulation 1272/2008)		
Is the adhesive or surface treatment classified with any of the hazard codes below? Including all classification variants (e.g. H350 also includes H350i).	**YES**	**NO**
H400 – Aquatic Acute 1		
H410 – Aquatic Chronic 1		
H411 – Aquatic Chronic 2		
H412 – Aquatic Chronic 3		
H413 – Aquatic Chronic 4		
H420 – Ozone		
H300 – Acute Tox. 1 or 2		

H310 – Acute Tox. 1 or 2		
H330 – Acute Tox. 1 or 2		
H301 – Acute Tox. 3		
H311 – Acute Tox. 3		
H331 – Acute Tox. 3		
H370 – STOT SE 1		
H371 – STOT SE 2		
H372 – STOT SE 3		
H373 – STOT SE 4		
H334 – Resp. Sens. 1, 1A or 1B		
H317 – Skin Sens. 1, 1A or 1B ***If yes** because of UV.cured acrylates-based adhesives or the hardener in 2-component adhesives, see below.*		
H350 – Carc. 1A or 1B		
H351 – Carc. 2		
H340 – Muta. 1A or 1B		
H341 – Muta. 2		
H360 – Repr. 1A or 1B		
H361 – Repr 2		
H362 – Lact.		
EUH380 – ED HH 1		
EUH381 – ED HH 2		
EUH430 – ED ENV 1		
EUH431 – ED ENV 2		
EUH440 – PBT		
EUH441 – vPvB		
EUH450 – PMT		
EUH451 – vPvM		

For UV-cured acrylates-based adhesives with any classifications above are exempted if the UV-cured acrylates-based adhesives are cured in a closed production system where there is no direct contact/exposure between worker and the chemical product. This must be declared by the applicant of the ecolabelled product.		
H317 is exempted for the hardener in 2-component adhesives and UV-cured acrylates-based adhesives that do not come into contact with the medicinal solution or the patient during treatment. This must be declared by the applicant of the ecolabelled product.		
O12 Classifications of ingoing substances in adhesive and surface treatment (according to CLP regulation 1272/2008)		
Does the adhesive or surface treatment contain ingoing substances or impurities classified with any of the hazard codes below? Including all classification variants (e.g. H350 also includes H350i).	**Yes**	**No**
***If yes** to any classifications below because of photoinitiators in UV-cured acrylates-based adhesives or in UV-cured surface treatment, see below.*		
H420 – Ozone		
H372 – STOT RE 1		
H334 – Resp. Sens. 1, 1A or 1B *If yes because the hardener in 2-component adhesives, see below.*		
H317 – Skin Sens. 1, 1A or 1B ***If yes** because of UV-cured acrylates-based adhesives or the hardener in 2-component adhesives, see below.*		
H350 – Carc. 1A or 1B		
H351 – Carc. 2 *If yes because of 2-component adhesives with isocyanates, see below.*		
H340 – Muta. 1A or 1B		
H341 – Muta. 2		
H360 – Repr. 1A or 1B		
H361 – Repr 2 .		
H362 – Lact.		
EUH380 – ED HH 1		
EUH381 – ED HH 2		
EUH430 – ED ENV 1		
EUH431 – ED ENV 2		
EUH440 – PBT		
EUH441 – vPvB		
EUH450 – PMT		
EUH451 – vPvM		
For UV-cured acrylates-based adhesives or UV-cured surface treatment with any classifications above: Are the classifications due to photoinitiators?		

For 2-component adhesives with classifications H317 and/or H334: Are the classifications due to hardener?		
H317 and H334 are exempted for the hardener in 2-component adhesives that do not come into contact with the medicinal solution or the patient during treatment. This must be declared by the applicant of the Ecolabelled product.		
Isocyanates classified H351 is exempted in 2-component adhesives 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. This must be declared by the applicant of the Ecolabelled product.		
Photoinitiators classified with any above are exempted in UV-cured acrylates-based adhesives and in UV-cured surface treatment if adhesives/surface treatment are cured in a closed production system where there is no direct contact/exposure between worker and the chemical product. This must be declared by the applicant of the Ecolabelled product.		
H317 is exempted in UV-cured acrylates-based adhesives if it is cured in a closed production system where there is no direct contact/exposure between worker and the chemical product. This must be declared by the applicant of the Ecolabelled product		
O13 Excluded substances in adhesive and surface treatment		
Does the adhesive or surface treatment contain any of the following as ingoing substances?	**Yes**	**No**
Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate-list-table *For D4, D5 and D6 in silicone polymers, see below under O14.*		
PBT and vPvB as defined in REACH Annex XIII, including those under ECHA PBT assessment https://echa.europa.eu/da/pbt		
Potential or identified endocrine disruptors, listed in any of the following "Endocrine Disruptor Lists" List I; II and III		
Phthalates (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid, CAS NO. 88-99-3))		
Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS NO. 25013-16-5), butylated hydroxytoluene (BHT, CAS NO. 128-37-0), alkylphenol ethoxylates (APEOs) and other alkylphenol derivates (APD)		
Per- and polyfluoroalkyl substances (PFAS) PFAS is defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)		
Halogenated organic compounds		
Metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)		
Bisphenols and bisphenol derivatives, defined as 34 bisphenols identified by ECHA for further EU regulatory risk management due to known or potential endocrine disruption or reproductive toxicity. *EC/List No. 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5 (BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS, 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA)*		
Quaternary ammonium compounds, which are not readily aerobic biodegradable such as DTDMAC (CAS NO. 61789-80-8), DSDMAC (CAS NO. 107-64-2), DHTDMAC (CAS NO. 61789-72-8) and DADMAC (CAS NO. 7398-69-8)		
Volatile aromatic compounds (VAC) (volatile organic compounds containing one or more benzene rings)		
Nanomaterials/-particles* ** Nanomaterials/-particles are defined according to the EU Commission Recommendation on the Definition of Nanomaterial (2022/C 229/01)10: 'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; (c) the*		

particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.		
O14 Silicone in adhesive and surface treatment	**YES**	**NO**
Does the adhesive or surface treatment contain silicone or siloxanes? ***If yes**, fill out below.*		
Are D4, D5 or D6 a part of the adhesive and surface treatment?		
Please state number of impurities* of D4, D5 and D6 in the silicone fluids: *D4: Octamethylcyclotetrasiloxane, (CAS NO.556-67-2)* *D5: Decamethylcyclopenta-siloxane, (CAS NO.541-02-6)* *D6: Dodecamethylcyclohexasiloxane, (CAS NO.540-97-6)* D4: _____ ppm D5: _____ ppm D6: _____ 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.*		
Is test report showing the amount of D4, D5 and D6 in the silicone fluids according to test method for silicone fluids from CES-Silicones Europe* or any ISO/IEC 17025-validated GC-MS method achieving LOQs at or below 100 ppm attached? * *Quantification-of-residual-amounts-of-Volatile-Siloxanes-in-silicone-products_final.pdf*		
Is documentation for the analysis laboratory fulfils the general requirements of standard EN ISO/IEC 17025 or have official GLP status attached?		

If the answer to any of the above questions regarding ingoing substances or impurities is Yes, please provide the following information for each relevant substance: CAS NO. (where possible), chemical name, concentration (in ppm, % by weight or mg/kg). Also state whether the substance is present as an ingoing substance or impurity.

If the adhesive or surface treatment composition changes, a new declaration confirming compliance with the requirements must be submitted to Nordic Ecolabelling.

Place and date	**Company name**
Responsible person	**Signature of responsible person**
Telephone	**Email**

Appendix 7 Declaration from the applicant about packaging

To be completed by the applicant for a licence for the Nordic Swan Ecolabel.

Type of packaging	**YES**	**NO**
Primary packaging? *Primary packaging means the packaging of the product that is necessary until the point of user. In the case of sterile products, primary packaging is designed to maintain the sterility of the product resulting in one piece of the specific product per primary packaging. Non-sterile products can be packed in primary packaging per product, in a certain number of products or without any primary packaging. It depends on the product types and their need for protection.* *Small parts such as stables, plastic strips, closure clips and cords are exempted.*		
Secondary packaging? *Secondary packaging means the packaging of a certain number of products in their primary packaging (if used) for protection during transport and storage.*		
Tertiary packaging? *Tertiary packaging means the outer layer of packaging in which the product is distributed during their initial dispatch from the manufacturer of the product. Auxiliary packaging as wrapping film etc. for transportation pallets are excluded. Other packaging used in downstream distribution, including transport between distribution centres, retailers, or final customers is excluded.*		

Packaging name and/or item number (write all the names/numbers this declaration covers):
Components of the packaging (container, closure, lid):
Packaging material (type of plastic, board etc.). List all materials included in each component of the packaging:

For all packaging	**YES**	**NO**
Does the packaging or label contain halogenated plastics (e.g. PVC or PVDC), oxo-degradable plastic or biodegradable plastic?		
Does the packaging contain intentionally added PFAS*? ** PFASs are defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).*		
Is the packaging surface treated with PFAS*, either on the inside or on the outside of the packaging? ** PFASs are defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).*		
Is metal use in the packaging? Staples and other small parts are exempt.		

For primary packaging is exception of metal layer for barrier purposes to preserve a sterile barrier, minimize evaporation and/or improve product shelf life.		
For board and paper:		
Is the packaging marked with the FSC- or PEFC-logo? **If yes**, please attach documentation for certification.		
Does the packaging contain recycled wood raw material? **If yes**, please state amount (weight %):_____		
Does the packaging contain wood raw material from forests that are managed in accordance with sustainable forestry management principles established by FSC- or PEFC-schemes? **If yes**, please state amount (weight %):_____		
Does the packaging contain wood raw material covered by the FSC/PEFC control schemes (FSC controlled wood/PEFC controlled sources)? **If yes**, please state amount (weight %):_____		
For secondary packaging and tertiary packaging	**YES**	**NO**
Is the packaging made of monomaterial*? ** Monomaterial means one material type, e.g. cardboard or one type of plastic, e.g. PP. However, coloured packaging components made from PP are allowed to have up to 5% PE if it comes from the masterbatch.*		
If the packaging is not made of monomaterial: Is each packaging component made of monomaterial? Small parts such as plastic strips, closure clips and cords are exempt.		
If the packaging is not made of monomaterial: Can each packaging component be sorted separately for recycling* without using a tool (including sorting into different plastic types)? Small metal parts (e.g. staples) are exempt. ** Energy recovery does not qualify as recycling.*		
If the packaging is not made of monomaterial: Are packaging components made of different materials glued or welded together?		
Has carbon black been added to any plastic components?		

Place and date	Company name
Responsible person	Signature of responsible person
Telephone	Email

Appendix 8 Declaration from the manufacturer/supplier of packaging

To be used in conjunction with an application for a licence for the Nordic Swan Ecolabel of a product.

Manufacturer/supplier:
Packaging component name and/or item number (write all the names/numbers this declaration covers):
Component of the packaging (e.g. container, lid):
Packaging material (type of plastic, board etc.). List all materials included in the packaging component: (Small parts such as stables, plastic strips, closure clips and cords are exempted.)

For all packaging	**YES**	**NO**
Does the packaging or label contain halogenated plastics (e.g. PVC or PVDC), oxo-degradable plastic or biodegradable plastic?		
Does the packaging contain metal?		
Does the packaging contain intentionally added PFAS*? ** PFASs are defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).*		
Is the packaging surface treated with PFAS, either on the inside or on the outside of the packaging? ** PFASs are defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).*		
For board or paper packaging	**YES**	**NO**
Is the packaging marked with the FSC- or PEFC-logo? **If yes**, please attach documentation for certification.		
Does the packaging contain recycled wood raw material? **If yes**, please state amount (weight %):_____ **If yes**, please attach documentation, e.g. invoices or delivery notes from suppliers.		

Does the packaging contain wood raw material from forests that are managed in accordance with sustainable forestry management principles established by FSC- or PEFC-schemes? **If yes**, please state amount (weight %):_____ **If yes**, please attach documentation, e.g. invoices or delivery notes from suppliers.		
Does the packaging contain wood raw material covered by the FSC/PEFC control schemes (FSC controlled wood/PEFC controlled sources)? **If yes**, please state amount (weight %):_____ **If yes**, please attach documentation, e.g. invoices or delivery notes from suppliers.		
For plastic packaging	**YES**	**NO**
Has carbon black been added to the component?		

Place and date	Company name
Responsible person	Signature of responsible person
Telephone	Email