



New criteria for Nordic
Swan Ecolabelled
medical devices and
medicinal products in
plastic and silicon



Agenda

Introduction to the Nordic Swan Ecolabel with market insights

New criteria for Medical devices and medicinal products in plastic and silicone 098

Application process – for renewal of licence and new application

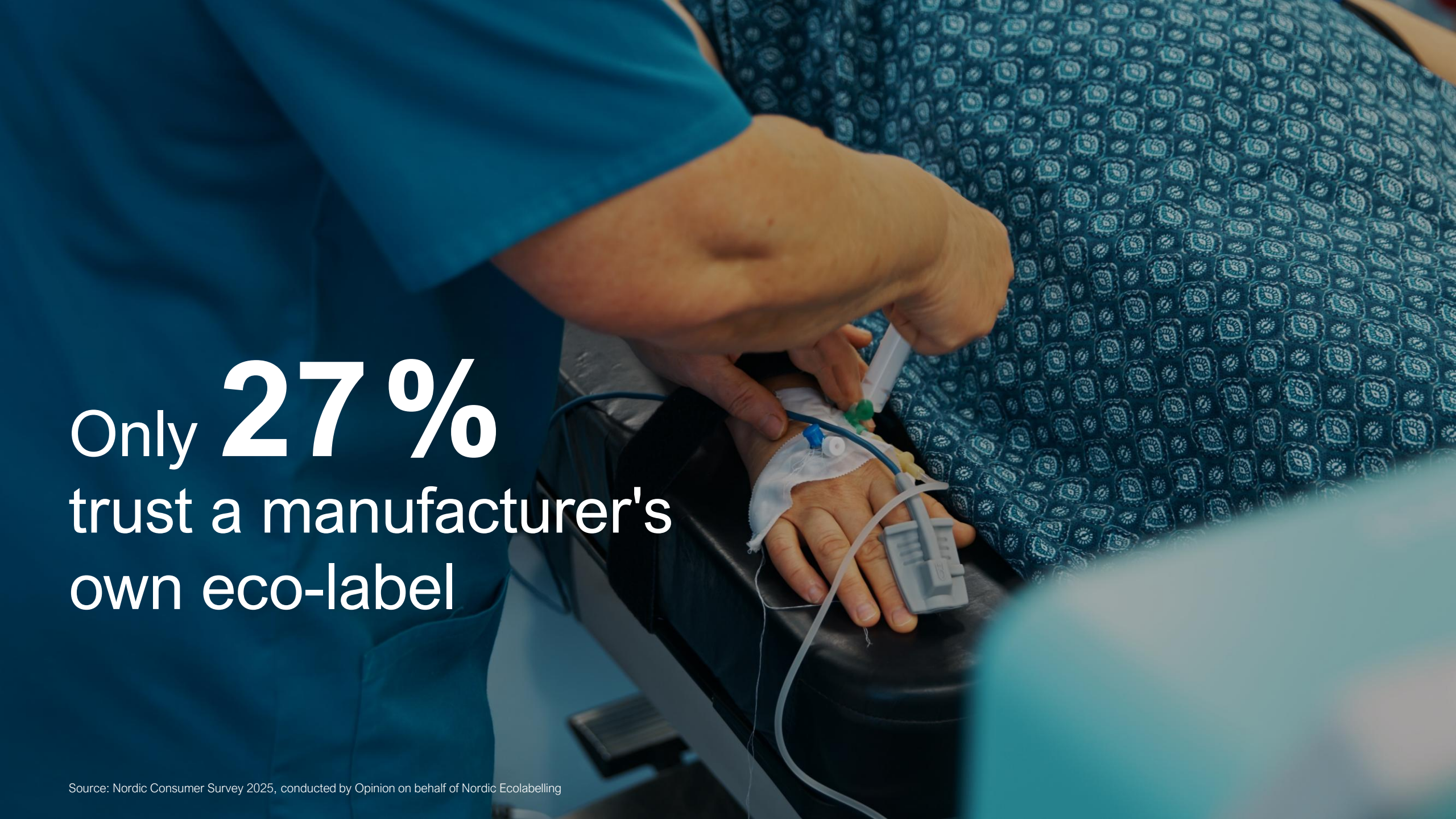
Q&A





Hard to get.
Easy to choose.





Only **27%**
trust a manufacturer's
own eco-label

8 of 10

Trust that a product does not contain health or environmentally harmful substances if it is labelled with the Nordic Swan Ecolabel.



A photograph of an elderly woman with white hair, smiling and swinging on a swing set in a park. The background is a soft-focus green landscape. The text '80%' is overlaid in large white font on the left side of the image.

80%

of the Nordic consumers
want the public sector to
prioritize environmental
labelling in procurement

Public procurement

Sweden 2023*

1009

billion SEK

How can these become “greener”?

We guide

We support

We motivate

”

We do not have the expertise to develop our own environmental requirements, and we do not have the capacity to control suppliers and their production. It therefore provides great security for us to use eco-labels, such as the Nordic Swan Ecolabel, in our procurements

Heidi Rygg. Purchasing Manager, Bærum Municipality

Public procurement as a strategy for smart and sustainable growth

Labels represent an important element of legal simplification for both public buyers and economic operators in the transition towards a systematic use of sustainability considerations in public procurement.



The Nordic Swan Ecolabel simplifies for procurers



Public procurers are increasingly looking for ecolabelled products

The Nordic Swan Ecolabel procurement support

- SE: [Så får ni ut det mesta av er licens vid offentlig upphandling](#)
[Inköp & upphandling – så ställer du krav på miljömärkning | Svanen](#)
- NO: <https://svanemerket.no/gronne-anskaffelser/>
- DK: <https://www.svanemaerket.dk/erhverv/offentlig-indkober>
- FI: <https://joutsenmerkki.fi/hankkijoille/julkiset-hankinnat/>
- IS: <https://svanurinn.is/>

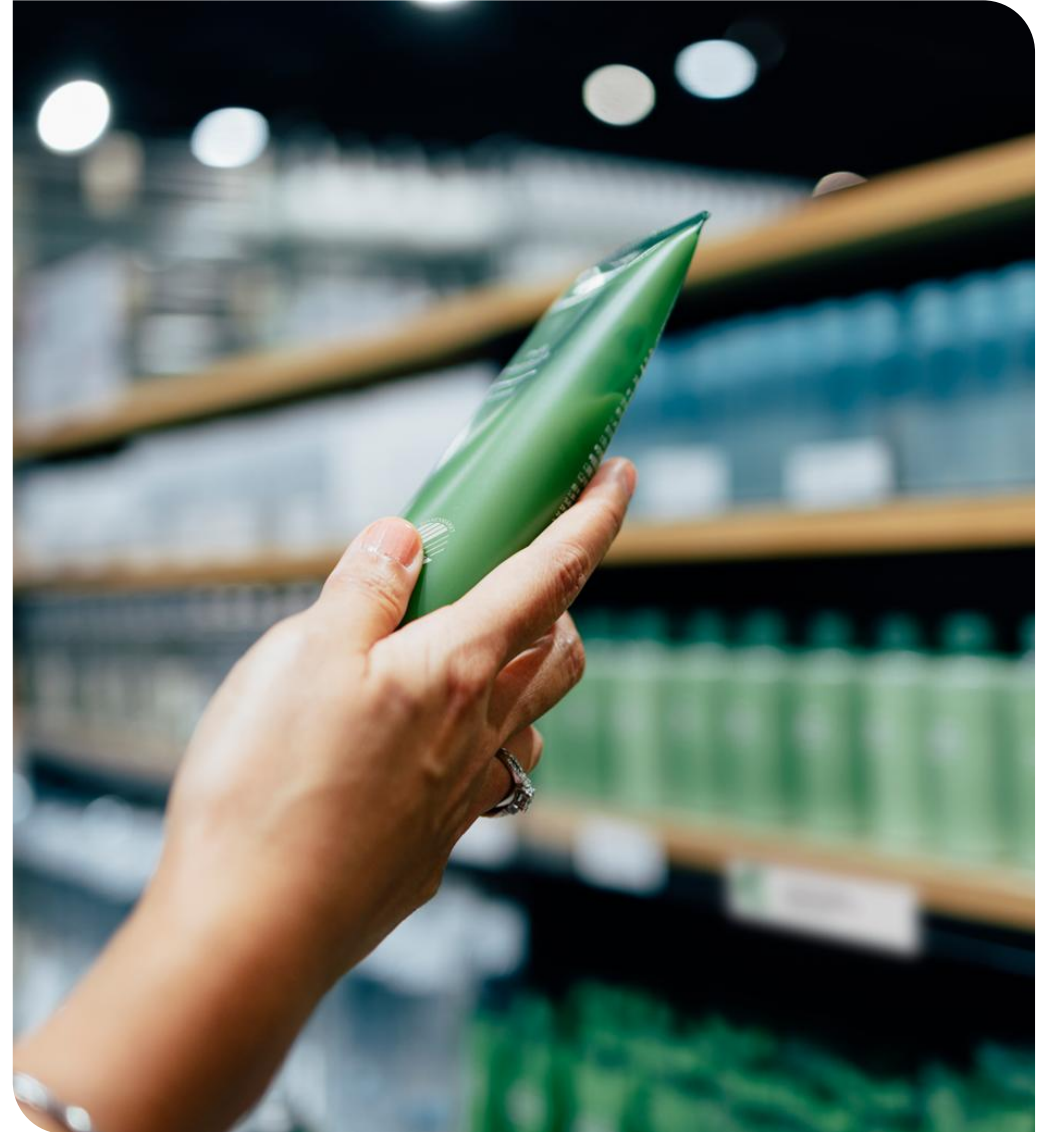
Green Deal & Clean Industrial Deal

EU strategy for the Green Transition



Empowering consumers directive: Simplifying green choices

- ✓ Controls lifespan, warranty time and repairability.
- ✓ Prohibits vague or irrelevant environmental claims.
- ✓ Regulates general environmental claims.
- ✓ Eco-labels must be officially recognised or approved by a third party.
- ✓ Valid from September 2026.



Eco-labelling in the Empowering Consumers Directive

- ✓ Type 1 ecolabels such as the Nordic Swan Ecolabel and the EU Ecolabel may be used to show "recognised excellent environmental performance"
- ✓ Companies are allowed to use these labels in their marketing without extra explanatory information
- ✓ The environmental claim must be linked to the criteria



What can you claim as Nordic Swan Ecolabelled?

There must be a connection to the criteria

An example: A Nordic Swan Ecolabelled medical device and medicinal product:

- ✓ Uses chemicals that meet tough environmental and health requirements
- ✓ Are not made of halogenated plastics (e.g. PVC, PTFE), rubbers and latex.
- ✓ Have no added phthalates, PFAS, bisphenols, identified and potential endocrine disruptors.



**Make a good choice
for the environment**

We offer Nordic Swan Ecolabelled
medical devices and medicinal
products in plastic and silicon

Type 1 ecolabel (according to the ISO 14024 standard)

The official ecolabel of the Nordic countries





40 000

Nordic Swan Ecolabelled products and services



Many companies and brands
offers The Nordic Swan Ecolabel



A woman with a braid, wearing a light green tank top and shorts, is walking on a dark sand beach holding the hand of a small child in a striped shirt. They are walking away from the camera towards the ocean. The background is a calm sea under a hazy sky.

96 %

of Nordic consumers
recognize the Nordic
Swan Ecolabel

81 %

trust that a Nordic Swan
Ecolabelled product is a
good choice for the
environment



The Nordic Swan Ecolabel has helped communicate and reinforce our sustainability profile, which is increasingly relevant in customer conversations, tenders, and patient decision-making.

While it has not always been the sole reason for commercial success, it has helped support our broader commitment to environmentally responsible dialysis care and aligns with growing stakeholder interest in sustainable healthcare.

We see it materialize especially in the European markets like the Nordics, Benelux or UK, where environmental requirements are more developed and for evaluation criteria in tenders or customers' or healthcare professionals' product/system selection.

Fredrik Gustafsson, VP CE International Commercial Operations EMEA West, Subregion Nordics & Baltics, Poland & Slovakia, Czech and BeNeLux, Fresenius Medical Care



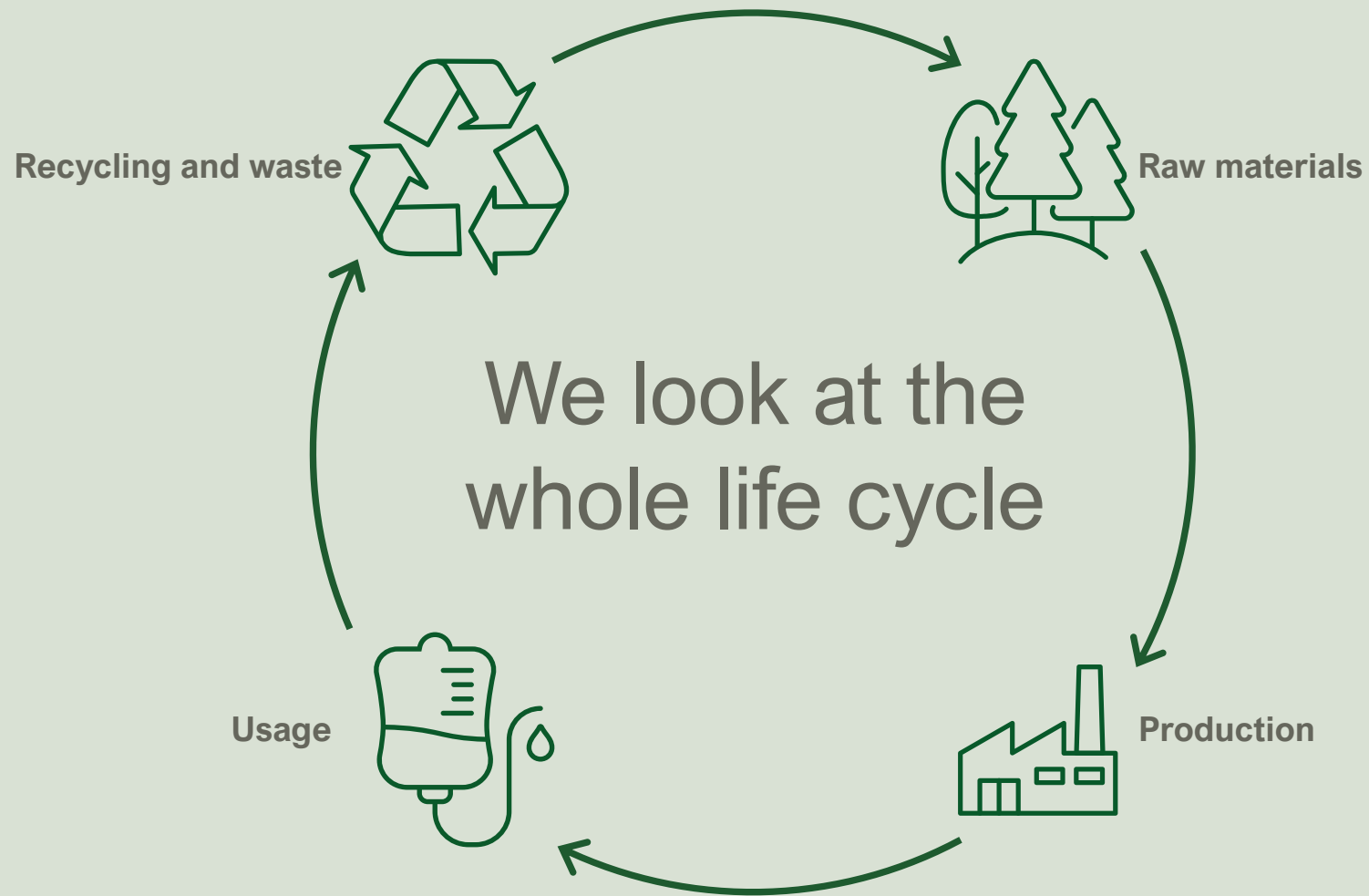
You are given the
right to use the
Nordic Swan Ecolabel



It's not just a right –
it's a great opportunity



Our goal is to move entire
industries in a more
sustainable direction



You can trust the Nordic Swan Ecolabel

The Swan is a Type 1 ecolabel



This means that we comply with an official ISO standard 14024 which requires us to be independent, that our requirements are transparent and available to all, that the requirements are tightened and have a life cycle perspective.

Independent & non-profit



The Swan is the Nordic's official environmental label and works on behalf of the five Nordic governments. The Swan's requirements are decided by an independent Nordic environmental labelling board.

Holistic & life-cycle perspective



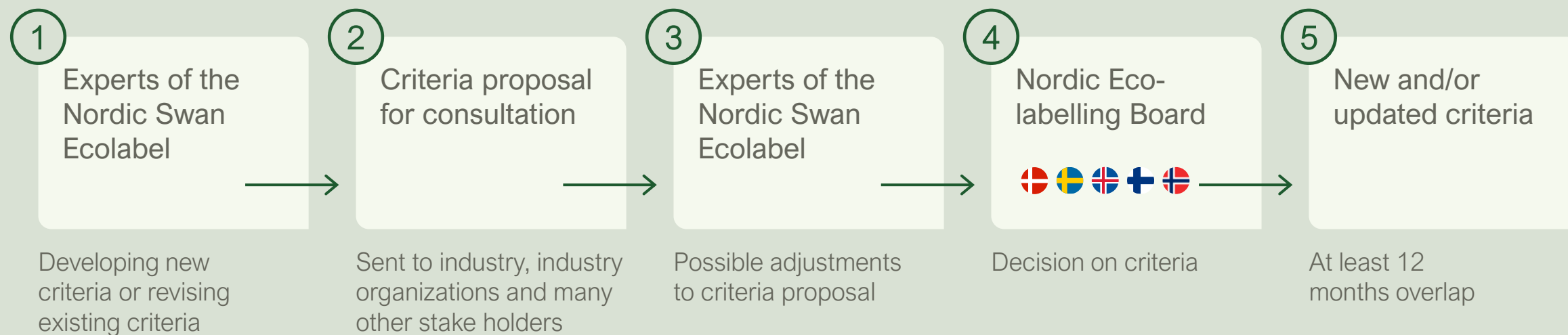
The Swan's requirements are based on a life cycle perspective. We assess the environmental impact on everything from raw materials and manufacturing to use and, for example, whether it can be recycled or how the waste is handled.

Time-limited criteria



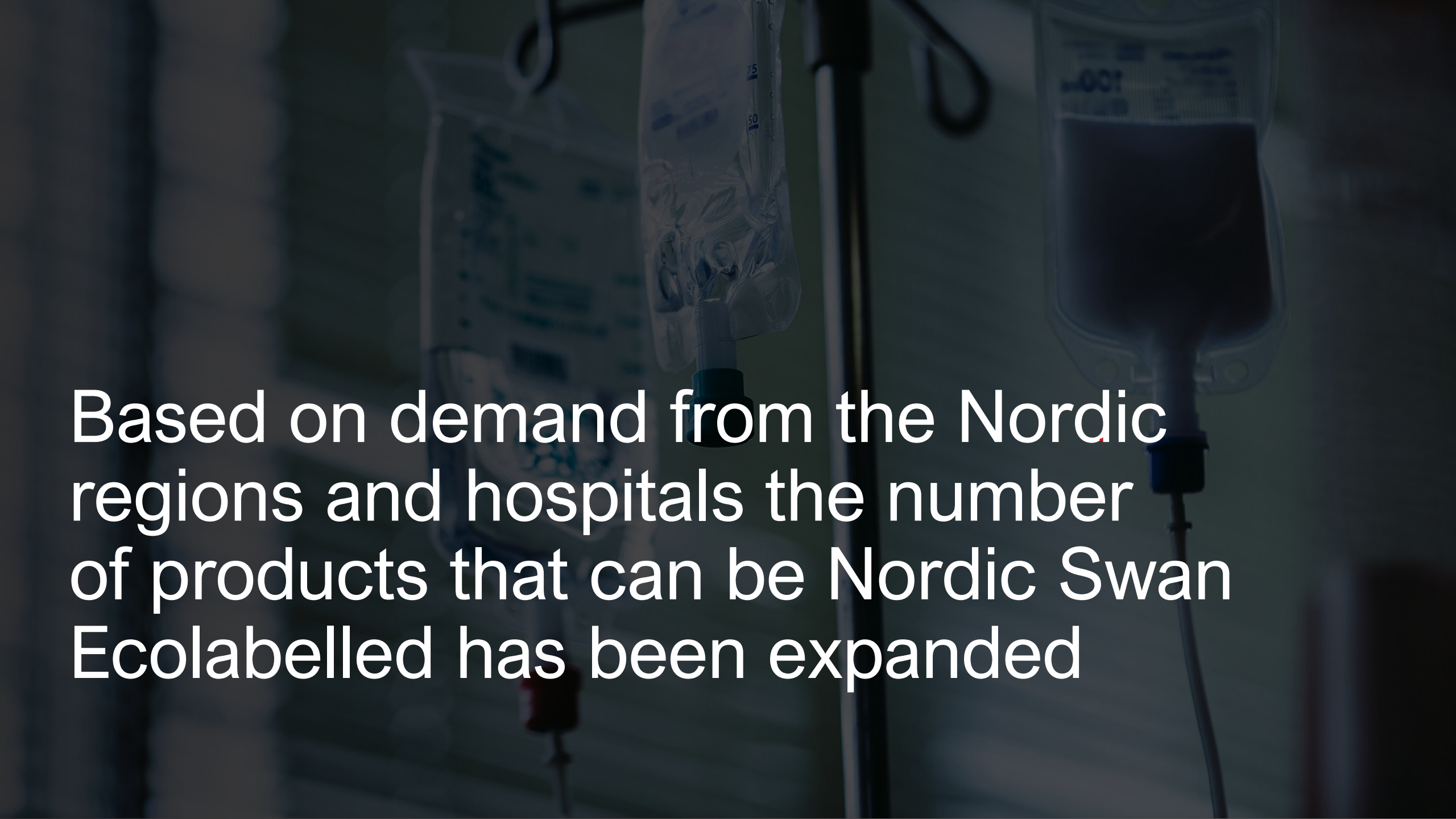
We evaluate the Swan's requirements after 3-4 years and tighten, update the requirements after 5 years, with new knowledge from researchers, independent experts and companies that lead sustainability development in their industries.

How does it work when the Nordic Swan Ecolabel's criteria are developed or revised?





Criteria for 098 Medical devices and medicinal products in plastic and silicone

The background of the slide is a dark, blurred photograph of medical equipment. It shows several clear plastic drip chambers hanging from a metal stand. The chambers are connected to clear plastic tubing. The lighting is dim, creating a clinical and somewhat somber atmosphere. The text is overlaid on the left side of the image.

Based on demand from the Nordic regions and hospitals the number of products that can be Nordic Swan Ecolabelled has been expanded

What can be Nordic Swan Ecolabelled

The product group includes



Masks

- Oxygen mask
- Anaesthesia mask
- Laryngeal mask
- Oxygen halter
- Breathing balloon set



Flexible tubes

- Urine catheter
- Vein catheter
- Umbilical catheter
- Intravenous infusion treatment
- Intestinal tube
- Gastric tube
- Duodenal tube
- Tracheal tube
- Pharyngeal tube
- Nasal tube
- Suction hose
- Drainage



Bags

- Blood bag
- Urine bag
- Drainage bag
- Suction bag
- Ostomy pouch
- Dialysis treatment bag



Plugs

- Anal plug
- Continence support
- Prolapse ring



Syringes

- Empty syringes
- Syringes prefilled with saline or water

Environmental benefits for medical devices and medicinal products

- ✓ Are not made of halogenated plastics, rubbers and latex.
- ✓ Meet strict requirements concerning chemicals that are hazardous to health and harmful to the environment.
- ✓ Packaging design and materials that promote recycling.
- ✓ Products mainly made of silicone (min. 80 w%) have reduced emissions to air and water during manufacturing.

Focus areas for the criteria of medical devices and medicinal products

-  General Product Requirements
-  Silicone and silicone production
-  Halogenated plastics (e.g. PVC, PTFE), halogenated butyl rubber and latex not allowed
-  Energy requirements concerning manufacturers that sterilize the final product
-  Chemical requirements for additives, adhesives and surface treatment
-  Packaging
-  For example: PFAS, phthalates and endocrine disruptors are not allowed
-  Licence Maintenance

Criteria – 20 mandatory requirements

Section 1 - Product and materials (5)

1. Description of the product
2. Halogenated plastics
3. Halogenated butyl rubber
4. Natural rubber latex
5. Silicone

Section 2 - Silicone production (3)

6. Emissions of dust and chlorides to air
7. Emissions of copper and zinc to water
8. Energy consumption for silicone

Section 3 - Additives in polymer materials (2)

9. Classification of ingoing substances in additives
10. Excluded substances in additives

Section 4 - Adhesive and surface treatment (4)

11. Classification of adhesive and surface treatment
12. Classification of ingoing substances in adhesive and surface treatment
13. Excluded substances in adhesive and surface treatment
14. Silicone in adhesive and surface treatment

Section 5 - Energy (1)

15. Energy management

Section 6 - Packaging (2)

16. Packaging materials
17. Packaging design for recycling

Section 7 - Safety (1)

18. Safety

Section 8 - Licence maintenance (2)

19. Customer complaints
20. Traceability

Criteria – 20 mandatory requirements

Section 1 - Product and materials (5)

1. Description of the product
2. Halogenated plastics
3. Halogenated butyl rubber
4. Natural rubber latex
5. Silicone

Section 2 - Silicone production (3)

6. Emissions of dust and chlorides to air
7. Emissions of copper and zinc to water
8. Energy consumption for silicone

Section 3 - Additives in polymer materials (2)

9. Classification of ingoing substances in additives
10. Excluded substances in additives

Section 4 - Adhesive and surface treatment (4)

11. Classification of adhesive and surface treatment
12. Classification of ingoing substances in adhesive and surface treatment
13. Excluded substances in adhesive and surface treatment
14. Silicone in adhesive and surface treatment

Section 5 - Energy (1)

15. Energy management

Section 6 - Packaging (2)

16. Packaging materials
17. Packaging design for recycling

Section 7 - Safety (1)

18. Safety

Section 8 - Licence maintenance (2)

19. Customer complaints
20. Traceability



Deep dive section 1

Product and materials

- ✓ Description of the product, product category, applicable legislation, information regarding different components.
- ✓ Halogenated plastics e.g. PVC, PVDC and PTFE not allowed.
- ✓ Halogenated butyl rubber e.g. bromobutyl rubber not allowed.
- ✓ Natural rubber latex not allowed.
- ✓ Silicon material must be medical grade or tested according to standards.

Criteria – 20 mandatory requirements

Section 1 - Product and materials (5)

1. Description of the product
2. Halogenated plastics
3. Halogenated butyl rubber
4. Natural rubber latex
5. Silicone

Section 2 - Silicone production (3)

6. Emissions of dust and chlorides to air
7. Emissions of copper and zinc to water
8. Energy consumption for silicone

Section 3 - Additives in polymer materials (2)

9. Classification of ingoing substances in additives
10. Excluded substances in additives

Section 4 - Adhesive and surface treatment (4)

11. Classification of adhesive and surface treatment
12. Classification of ingoing substances in adhesive and surface treatment
13. Excluded substances in adhesive and surface treatment
14. Silicone in adhesive and surface treatment

Section 5 - Energy (1)

15. Energy management

Section 6 - Packaging (2)

16. Packaging materials
17. Packaging design for recycling

Section 7 - Safety (1)

18. Safety

Section 8 - Licence maintenance (2)

19. Customer complaints
20. Traceability



Deep dive section 2 Silicone production

- ✓ The manufacturer of the silicone need to take measures to reduce emissions of dust and chlorides to air
- ✓ The water effluents need to be pretreated
- ✓ Energy consumption data must be reported for the production site of the silicone

Criteria – 20 mandatory requirements

Section 1 - Product and materials (5)

1. Description of the product
2. Halogenated plastics
3. Halogenated butyl rubber
4. Natural rubber latex
5. Silicone

Section 2 - Silicone production (3)

6. Emissions of dust and chlorides to air
7. Emissions of copper and zinc to water
8. Energy consumption for silicone

Section 3 - Additives in polymer materials (2)

9. Classification of ingoing substances in additives
10. Excluded substances in additives

Section 4 - Adhesive and surface treatment (4)

11. Classification of adhesive and surface treatment
12. Classification of ingoing substances in adhesive and surface treatment
13. Excluded substances in adhesive and surface treatment
14. Silicone in adhesive and surface treatment

Section 5 - Energy (1)

15. Energy management

Section 6 - Packaging (2)

16. Packaging materials
17. Packaging design for recycling

Section 7 - Safety (1)

18. Safety

Section 8 - Licence maintenance (2)

19. Customer complaints
20. Traceability



Deep dive section 3

Additives in polymer materials

- ✓ E.g. plasticisers, colourants, antioxidants etc.
- ✓ Classification and excluded substances.
- ✓ **All** ingoing substances in the additives should be declared and needs to fulfil the requirements separately, regardless of the amount of the substance in the additive.
- ✓ For impurities (e.g. residues from production) there is a specific defined limit.

Example

Blue colouring additive

	Function	Quantity in %
Substance 1	Pigment	10%
Substance 2	Thickener	3%
Substance 3	Binder	0,8%
Substance 4	UV stabilizer	0,005% (50 ppm)

Criteria – 20 mandatory requirements

Section 1 - Product and materials (5)

1. Description of the product
2. Halogenated plastics
3. Halogenated butyl rubber
4. Natural rubber latex
5. Silicone

Section 2 - Silicone production (3)

6. Emissions of dust and chlorides to air
7. Emissions of copper and zinc to water
8. Energy consumption for silicone

Section 3 - Additives in polymer materials (2)

9. Classification of ingoing substances in additives
10. Excluded substances in additives

Section 4 - Adhesive and surface treatment (4)

11. Classification of adhesive and surface treatment
12. Classification of ingoing substances in adhesive and surface treatment
13. Excluded substances in adhesive and surface treatment
14. Silicone in adhesive and surface treatment

Section 5 - Energy (1)

15. Energy management

Section 6 - Packaging (2)

16. Packaging materials
17. Packaging design for recycling

Section 7 - Safety (1)

18. Safety

Section 8 - Licence maintenance (2)

19. Customer complaints
20. Traceability



Deep dive section 4

Adhesive and surface treatment

- ✓ Requirement for the classification of the adhesive and/or surface treatment
- ✓ Classification of **all** ingoing substances in the adhesive/surface treatment, despite the amount of the substance in the adhesive/surface treatment.
- ✓ Excluded substances of **all** ingoing substances in the adhesive/surface treatment, regardless of the amount of the substance in the adhesive/surface treatment.
- ✓ Silicone in adhesives and surface treatment

Criteria – 20 mandatory requirements

Section 1 - Product and materials (5)

1. Description of the product
2. Halogenated plastics
3. Halogenated butyl rubber
4. Natural rubber latex
5. Silicone

Section 2 - Silicone production (3)

6. Emissions of dust and chlorides to air
7. Emissions of copper and zinc to water
8. Energy consumption for silicone

Section 3 - Additives in polymer materials (2)

9. Classification of ingoing substances in additives
10. Excluded substances in additives

Section 4 - Adhesive and surface treatment (4)

11. Classification of adhesive and surface treatment
12. Classification of ingoing substances in adhesive and surface treatment
13. Excluded substances in adhesive and surface treatment
14. Silicone in adhesive and surface treatment

Section 5 - Energy (1)

15. Energy management

Section 6 - Packaging (2)

16. Packaging materials
17. Packaging design for recycling

Section 7 - Safety (1)

18. Safety

Section 8 - Licence maintenance (2)

19. Customer complaints
20. Traceability



Deep dive section 5 & 6 Energy & Packaging

- ✓ The manufacturing sites that perform sterilization of the final product must actively work with energy savings according to standards. Including an action plan to reduce energy consumption.
- ✓ Requirements for primary, secondary and tertiary packaging
- ✓ Halogenated plastic, biodegradable plastic and metals must not be used
- ✓ A minimum of 70% of the wood raw material in the paper- and board must be recycled or covered by FSC- or PEFC-schemes
- ✓ Must not contain PFAS

Criteria – 20 mandatory requirements

Section 1 - Product and materials (5)

1. Description of the product
2. Halogenated plastics
3. Halogenated butyl rubber
4. Natural rubber latex
5. Silicone

Section 2 - Silicone production (3)

6. Emissions of dust and chlorides to air
7. Emissions of copper and zinc to water
8. Energy consumption for silicone

Section 3 - Additives in polymer materials (2)

9. Classification of ingoing substances in additives
10. Excluded substances in additives

Section 4 - Adhesive and surface treatment (4)

11. Classification of adhesive and surface treatment
12. Classification of ingoing substances in adhesive and surface treatment
13. Excluded substances in adhesive and surface treatment
14. Silicone in adhesive and surface treatment

Section 5 - Energy (1)

15. Energy management

Section 6 - Packaging (2)

16. Packaging materials
17. Packaging design for recycling

Section 7 - Safety (1)

18. Safety

Section 8 - Licence maintenance (2)

19. Customer complaints
20. Traceability



Deep dive section 7 & 8

Safety & Licence maintenance

- ✓ Both products and parts must be safe to use and function well according to EU Medical Devices Regulation (2017/745) or EU Medicinal Products Directive (2001/83/EC).
- ✓ For medical devices: CE marking shall be visible on the label.
- ✓ The manufacturing site of the final product must be certified according to a specific quality standard.
- ✓ The licensee must guarantee that the quality of the Nordic Swan Ecolabel product does not deteriorate during the validity period of the licence.
- ✓ The licensee must be able to trace the Nordic Swan Ecolabel products in the production.

The application process



Requirements

*Requirement
number and header*

Requirement description

Needed documentation

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.

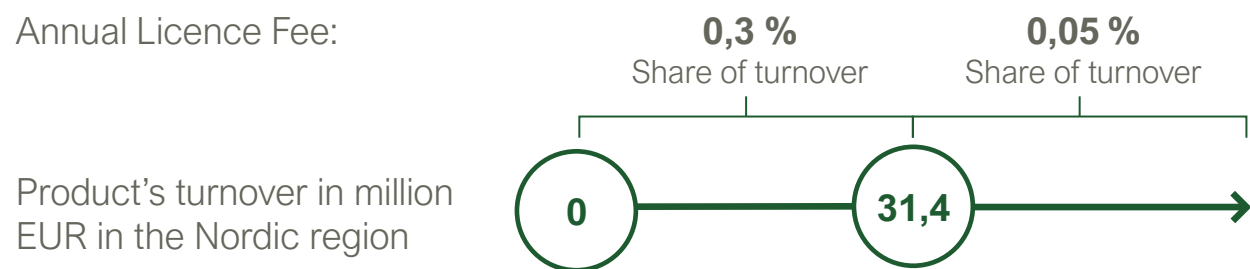
Fees (2026)

Application fee:

3 401 EUR for new licence

1 699 EUR for renewal of current license to revised criteria

Annual Licence Fee:



Minimum annual fee (independent of sales):

2 267 EUR

For turnover > 300 000 EUR outside the Nordic region:

2 267 EUR

On-site inspection outside the Nordics:

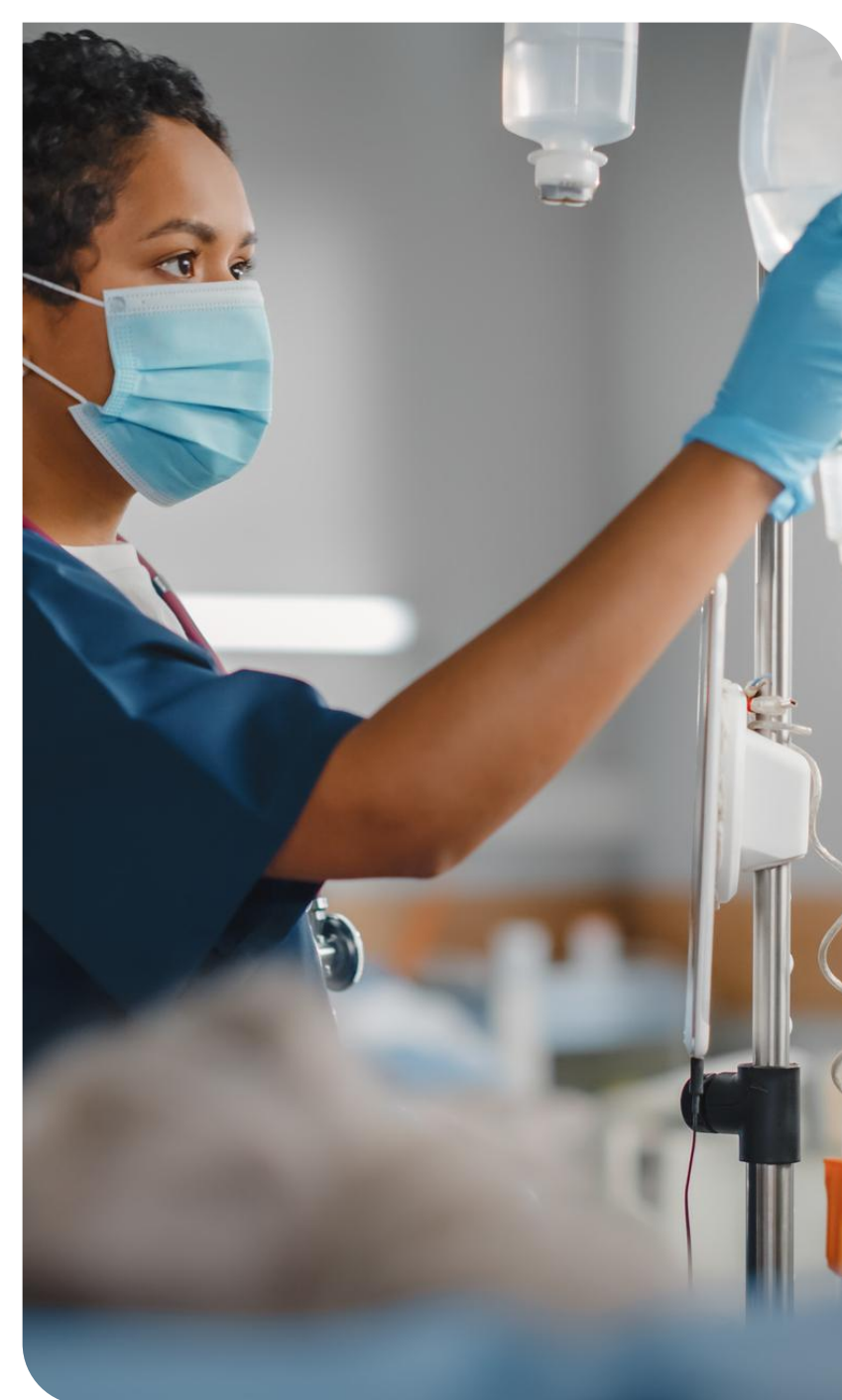
1 699 EUR

On-site inspection outside Europe:

2 834 EUR

Changes or extensions of licence (work time based):

424 / 849 / 1699 EUR



Start now!

What to think of regarding your documentation

- ✔ Start collecting documentation as soon as possible, especially from your suppliers.
- ✔ Use our writable declarations. (Other formats may be accepted.)
- ✔ Suppliers: Read the relevant requirements for you and prepare the writable declarations and other required documentation.
- ✔ Activate your (renewal) application in the portal.
- ✔ Upload everything in the application portal, in short & appropriately named files and in the correct folder.



Start-up meeting

Contact

Denmark

Simon Lyhne Andersen

Product specialist

sla@ecolabel.dk

Tina Toft Olsen

Sales

to@ecolabel.dk

svanemaerket.dk

Finland

Annika Hämäläinen

Product Specialist

annika.hamalainen@ecolabel.fi

Mari Halmineva

Sales

mari.halmineva@ecolabel.fi

joutsenmerkki.fi

Norway

Barkha Agrawal

Product Specialist

ba@svanemerket.no

Bjørn Olav A Strandli

Sales

bos@svanemerket.no

svanemerket.no

Sweden

Ulf Eriksson

Product Specialist

ulf.eriksson@svanen.se

Wilma Bäckström Nilsson

Sales

wilma.nilsson@svanen.se

svanen.se