Joint Nordic Industry Consultation Response, Swedish Medtech, Melanor, Medicoindustrien and Sailab, on the Proposed Criteria for the Nordic Swan Ecolabel for Medical devices in plastic or silicone (098)

6 February 2026

The Nordic industry associations Swedish Medtech (Sweden), Melanor (Norway), Medicoindustrien (Denmark) and Sailab (Finland) wish to submit comments on the proposed new criteria for the Nordic Swan Ecolabel for medical devices made of plastic and silicone. The industry shares the ambition to reduce environmental impact and continuously works to improve sustainability through international standards, supplier requirements and the EU regulatory framework. At the same time, we would like to highlight several overarching aspects that are important to consider in the further development of the criteria.

Background: EU regulatory framework for medical devices (MDR)

Medical devices placed on the EU market are subject to comprehensive, binding regulation under the EU Medical Device Regulation (MDR) (Regulation (EU) 2017/745), which ensures harmonised requirements at EU level so that products can circulate freely within the Union and that patients have access to safe and appropriate medical devices. This is particularly important as medical technology is, in most cases, developed and manufactured in a global market.

MDR establishes harmonised, legally binding requirements across the European Union governing patient safety, material selection and biocompatibility, chemical and biological safety, device performance, traceability, risk management, technical documentation, and post-market surveillance. These requirements apply throughout the entire device lifecycle and form the basis for conformity assessment. The regulation covers not only manufacturing but also classification of products, with detailed provisions on how products should be risk-classified (Class I, IIa, IIb and III) and how they should be certified. For most risk classes, assessment by a Notified Body and certification are required; the higher the risk class, the more extensive the requirements.

Product modifications including design alterations, changes to materials, formulations, or manufacturing processes, including those driven by environmental criteria, are treated under MDR as significant or substantial modifications. Such changes typically require extensive revalidation, including updated technical documentation, biocompatibility and chemical testing, stability and sterility studies, potential clinical evidence, and review by a Notified Body. Material changes are regarded by both MDR and Notified Bodies as one of the most critical types of modifications. As a result, they often lead to extensive testing and new regulatory assessments. These processes are time-consuming and resource-intensive, often taking several years to complete and incurring substantial cost per product family. MDR certification or recertification usually ranges between EUR 20,000 and EUR 60,000 per product family, and considerably more for higher-risk categories.

Market impact, cost, and availability

The cumulative effect of additional, market-specific sustainability requirements must be carefully assessed. Experience under MDR already shows that increased regulatory burden has contributed to the withdrawal of low-margin, niche, and paediatric devices and consumables from the European market. Introducing additional voluntary criteria that require product-specific certification,

documentation, labelling, or manufacturing adjustments risks exacerbating this trend, particularly in smaller markets as the Nordics.

Reduced product availability, higher costs, or reliance on older treatment methods may ultimately affect healthcare providers and patients. It is important to bear in mind that manufacturers cannot rapidly adapt regulated medical devices to evolving voluntary environmental criteria without risking regulatory non-compliance, supply disruption or market withdrawal.

Differences Between the Consumer Market and the Professional Healthcare Market

It is also important that the Nordic Swan Ecolabel recognises the fundamental differences between consumer products and medical devices intended for professional use in healthcare. Unlike consumer goods, medical devices are not only highly regulated but these products are used in critical care settings, often under sterile conditions and in direct patient contact. As a result, the prerequisites, risks, possibilities for modification, market dynamics and product life cycles differ significantly from those of the consumer market. Applying criteria or assumptions derived from the consumer sector therefore risks resulting in conclusions that are not aligned with the regulatory reality, or that inadvertently undermine the availability of medical technology.

Single-point-of-failure scenarios

While the Nordic Swan Ecolabel is a voluntary scheme, experience across Nordic healthcare procurement indicates a growing risk that ecolabel criteria are applied de facto as mandatory requirements or dominant award drivers in public tenders for medical devices. Procurement approaches that narrow the supplier base through reliance on a single certification pathway increase the risk of *single-point-of-failure scenarios*. Any disruption affecting the remaining supplier, whether regulatory, manufacturing, or logistical, can have immediate consequences for patient care. Supply security and continuity of treatment must therefore be weighed alongside environmental objectives when designing and applying sustainability criteria.

If ecolabel compliance becomes a dominant award factor in public tenders, suppliers may be disadvantaged despite full compliance with EU law. This could, in effect, shift a voluntary label into a position of de facto market access relevance without the legal safeguards, harmonisation or impact assessment that accompany formal regulatory requirements.

Transparency and dialogue

The Nordic industry associations Swedish Medtech, Melanor, Medicoindustrien and Sailab consider it is essential that broad and early dialogue with the industry takes place already before consultations are published. The industry is concerned that the proposed criteria group together very broad and heterogeneous product categories without sufficient differentiation by device risk class, clinical criticality, or regulatory complexity. Medical devices range from low-risk accessories to life-sustaining therapies with zero tolerance for interruption. Applying uniform environmental criteria across such diverse categories risks disproportionate impact on high-risk or clinically critical devices, where material flexibility is inherently limited by patient-safety requirements.

In several device categories, materials such as silicone or PVC may be clinically necessary to ensure biocompatibility, sterility, flexibility or mechanical performance. For certain applications, silicone may also represent the most sustainable option when considering durability, patient safety requirements and the full device lifecycle. Material choices in regulated medical technologies therefore cannot be made solely on the basis of generic environmental preferences, but must be grounded in clinical performance, risk management and MDR compliance.

Market Effects, Supply Continuity and the Importance of Thorough Assessments

In today's regulatory landscape, products are already being withdrawn from the market, leading to situations in which healthcare providers must rely on older treatment methods. This development illustrates how vulnerable the medical technology supply chain is and how quickly availability can be affected by additional requirements. Against this background, it is relevant to ask whether a risk assessment has been conducted regarding how further criteria, or consultations that do not consider all relevant aspects, may affect access to medical technologies.

The industry is supportive of initiatives that promote sustainable development, but considers that more comprehensive and transparent impact assessments are needed for the proposed criteria and this type of consultation. This is particularly relevant when assessing expected environmental benefits in relation to the costs, administrative burden and market effects that may arise, as well as potential impacts on the availability of medical devices and consumables.

Sustainability criteria must be assessed holistically. Requirements that drive country-specific manufacturing runs, bespoke labelling, or parallel supply chains risk increasing transport emissions, packaging waste, and manual handling, potentially offsetting intended environmental gains. In addition, deep upstream disclosure requirements may be infeasible in complex global supply chains, particularly where sub-suppliers cannot share proprietary or confidential information. These feasibility constraints should be explicitly considered in the design of criteria for regulated products

As medical products are critical components in essential healthcare processes, it is vital that procurement-related criteria do not lead to unintended consequences for product availability, functionality or patient safety, but also that they do not unintentionally offset or even reverse the intended environmental benefits.

Swedish Medtech
Anni Peltonen

Melanor
Hella Yngsdal

Medicoindustrien
Lene Laursen

Sailab
Kirsi Talman