Danish Regions

NORDIC CRITERIA FOR MORE SUSTAINABLE PACKAGING

FOR HEALTHCARE PRODUCTS

MAY 2026

CONTENTS

APPENDICES

Support tools

Support tools are available at: https://www.regioner.dk/regional-udvikling/groenne-hospitaler/indkoeb/emballagekriterierne/

Examples of packaging levels (in Danish): Illustrate examples of primary, secondary and tertiary packaging across different products, which can be used in market dialogue.

Scoring model for packaging (in English): A tool used for packaging criterion 1.3.

Market dialogue tool (in English): A tool for the contracting authority used in market dialogue. It provides an overview of which packaging criteria suppliers are able to comply with.

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Published on regioner.dk/regional-udvikling/groenne-hospitaler/indkoeb/emballagekriterierne/

1 Introduction

The Nordic Criteria for More Sustainable Packaging (The Packaging Criteria) for Healthcare Products aim to reduce climate and environmental impacts of packaging in the healthcare sector. The document contains a library of criteria for packaging that can be used in the tender process.

The Packaging Criteria have been developed in collaboration between stakeholders responsible for public green procurement in the health sector in Norway, Sweden, Denmark, Iceland and the Faroe Islands. The criteria have been circulated for consultation in the relevant industry organisations in Norway and Denmark as well as in the framework of Medtech Europe, the European industry association in 2022. The Packaging Criteria have most recently been updated based on the EU's Packaging and Packaging Waste Regulation[1], which was adopted in December 2024 (hereinafter Regulation 2025/40). The latest revision was consulted on with industry associations for medical devices in Norway, Sweden and Denmark in 2026.

The Packaging Criteria complies with the sector-specific legislation applicable to medical devices.

The intention of developing and implementing the joint Nordic packaging criteria is to strategically leverage the purchasing power inherent in public procurement in order to achieve improved packaging solutions, including within the healthcare sector, in accordance with the principles of the Regulation 2025/40. This means that the Packaging Criteria are designed to contribute to guiding market development in a more sustainable direction.

In the absence of established industry standards for more sustainable packaging in the healthcare sector, the Packaging Criteria therefore provide an approach to how the objectives of the Regulation can be translated into requirements in public procurement that are transparent, objective, and non-discriminatory.

The purpose of the criteria is to assist the relevant responsible persons for public sector tenders, e.g., category managers, public procurement officers or tender consultants in defining packaging-specific criteria relevant to the specific procurement. Health sector suppliers in the Nordics may find it useful to familiarise themselves with the criteria to prepare for potential supplier requirements.

The packaging criteria are indicative and do not constitute legally binding standards. The criteria cannot replace the contracting authority’s own assessment of relevance, proportionality, security of supply, or compliance with applicable legislation, including sector-specific regulation for medical devices. It is recommended that the criteria be applied and adapted with due consideration to the specific procurement, the market situation, and the product’s function and risk profile.

[1] Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904 and repealing Directive 94/62/EC (hereinafter Regulation 2025/40).

1.1 Reading Guide

The document includes a guide to the tender consultant on how to use the criteria (section 3) and a library of criteria (section 4) which can be implemented in the tender documents as appropriate. Several appendices include additional information. The appendices are intended to be a work of references where tender consultants may find further technical information about the use of the criteria.

The first library of criteria was published in August 2022 and applied in several calls for tenders. Based on the experiences, the criteria and the guides have been revised in 2023. Following the approval of Regulation 2025/40, the packaging criteria have been revised to be consistent with the Regulation. The Regulation explicitly states that the provisions of the Regulation can be considered as minimum requirements and that public tenders may well set requirements that go beyond the provisions of Regulation 2025/40.

Several of the provisions of the Regulation are currently not yet defined in detail through delegated acts. This applies, for example, to how the performance requirements for recyclability of packaging can be determined, and the labelling of packaging through digital data carriers. In the common Nordic packaging criteria, these not yet defined details are handled by making requirements relating to such aspects spearhead competition criteria.

The main content of the latest revision consists of:

- The terminology regarding the various packaging criteria has been brought into line with Regulation 2025/40
- Regulation 2025/40's definition for actual recycling is implemented in the common Nordic packaging criteria
- The definition of actual recycling is supported with a positive and negative list for desired and unwanted materials
- The performance class principle, which indicates the extent to which a complete package can actually be recycled, has been implemented
- New spearhead criterion on the content of chemical substances in packaging
- New spearhead criterion for labelling packaging using digital data carriers
- New opportunity to work with innovation clauses in the contract
- The scoring model for packaging has been updated. The calculation basis has been updated with new data that has a more accurate energy mix. The scoring model also has more plastic types
- Biobased plastics have been updated, and it has been specified which certification schemes for biobased plastics are accepted

The Regulation 2025/40 is further briefly described in Appendix G.

2 More sustainable packaging for healthcare products

This chapter introduces two main topics:

- How to understand and delimit packaging for healthcare products, and
- What is the purpose of the library of criteria, and how to understand the concept of sustainability.

2.1 What is packaging for healthcare products?

The health sector uses products and associated packaging that is either sterile, clean or ordinary. To stipulate relevant requirements for packaging for healthcare products and to communicate sustainability requirements for packaging between the contracting entity and the tenderer, a common frame of understanding for packaging for healthcare products is needed.

The Packaging Criteria for the Healthcare Sector are based on the general terminology for ordinary packaging, cf. the Regulation 2025/40[2]:

- Sales packaging corresponds to primary packaging in the regulation
- Multipack packaging is equivalent to secondary packaging
- Transport packaging corresponds to tertiary packaging in the regulation

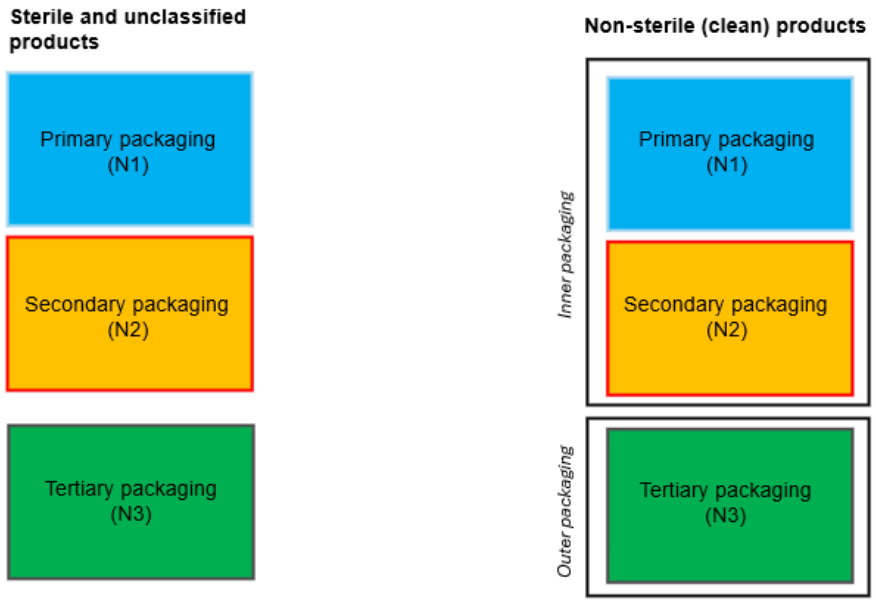


Figure 1 Packaging levels for sterile and clean products respectively

In general, **sterile packaging** consists of three layers, as described above. However, the functioning of the primary packaging for a sterile medical product is more complex than is the case with, e.g., a bag of potatoes. First and foremost, the purpose of the primary packaging is to ensure that the sterile

[2] Regulation 2025/40, Article 3, paragraph 1, points 4-7

product remains sterile until it is used. The packaging must allow for sterilisation through the packaging by means of various sterilisation methods, and it must be possible to open it with and without gloves to ensure that the product remains sterile.

Consequently, sterile primary packaging is technologically and material-wise complex. The requirements for sterile packaging and package systems for terminal sterilised medical equipment are stated in DS/EN 11607-1:2020, parts I and II. Annex D of the standard describes, in very overall terms, 'environmental considerations' as a topic of increasing importance. But the standard does not further specify how to handle 'environmental considerations' for sterile packaging. Packaging for **clean** (non-sterile) products is typically less complex. Clean packaging usually has two layers of packaging; the primary packaging layer protecting the product, and the outer packaging protecting the product and the primary packaging.

There may be national guidelines for how to describe packaging for healthcare products. Appendix D contains an overview of the terminology for sterile and non-sterile packaging that is used in the Danish Regions' contract appendix 5, which is linked to the general definition of packaging used in the European Packaging and Packaging Waste Directive.

Appendix C includes examples of types of packaging that may be used to start a market dialogue. The examples are intended to support the dialogue with tenderers, ensuring that all parties understand what the packaging is made of. *Also see the template 'Power point skabelon og eksempler på emballageniveauer'.*

In case of doubt as to whether a given part of the product, which resembles packaging, is in fact packaging, the following should be noted: An article which forms an integral part of a product and which is necessary to contain, support or preserve that product throughout its life, and where all the elements of that article are intended for use, consumption or disposal together, should not be considered packaging, as its functionality is inextricably linked to its being part of the product.[3] This means, among other things, that IV bags and pre-filled syringes are not considered packaging.

[3] Regulation 2025/40, Preamble 13

2.3 What is more sustainable packaging according to the joint Nordic criteria?

The overall purpose of using these criteria is to lower the climate and environmental impact of packaging, e.g., greenhouse gas emissions, in accordance with Regulation 2025/40.

However, the overall environmental and climate impact of packaging is very complex to calculate. The climate and environmental impact of packaging depends on the packaging's life cycle:

- selection and extraction of raw materials, consumption of raw materials, water and energy consumption in connection with manufacturing,
- emissions to water and air in connection with manufacturing,
- transportation,
- storage,
- use,
- material type and quantity,
- recyclability and disposal

The Packaging Criteria were developed as a tool for tender processes that may contribute to reducing the climate and environmental impact of packaging. The sustainability criteria for packaging were neither developed nor able to cover all aspects of the life cycle of a specific packaging. Using sustainability criteria may ensure that packaging with a smaller climate and environmental impact is in demand.

The sustainability criteria only deal with several selected sustainability topics. The topics were chosen based on the European Packaging and Packaging Waste Directive 94/62/EC and the latest revision (EU)2018/852, meaning that the criteria contribute to operationalising the European Packaging and Packaging Waste Directive. See further in Appendix G. The criteria are divided into the following three sustainability topics and elaborated on below:

1. Reduce material consumption
2. Design for recycling
3. Recycled or sustainably sourced materials content.

Reducing material consumption is usually the most effective measure when it comes to developing more environmentally friendly packaging. It reduces resource consumption and waste volumes. Furthermore, this sustainability topic offers economic advantages to producers.

Designing **packaging for sorting and recycling** also contributes to reducing the total resource consumption, since the recycled materials can be used for new products.

By **requesting recycled and bio-based materials**, the call for tenders contributes to reducing the dependency on fossil resources. Furthermore, bio-based materials also support the development of a bio-based economy. The challenge of bio-based materials, especially plastics, is that they may potentially come from raw materials that could have been used for foods (e.g., maize) or be grown

in areas that could have been used for food production. Consequently, it is important to pay attention to the origin of the biomass used to produce bio-based materials. In turn, it is crucial to ensure that the requested bio-based materials meet relevant standards.

Based on the chosen sustainability topics, the criteria may contribute to, in a systematic and provable manner, requesting *more* sustainable packaging in tender documents. To be reasonably accurate, the criteria place great emphasis on the quality of the documentation.

The criteria were developed to support the European Packaging and Packaging Waste Directive. That is also the source of the logic that is integrated into the criteria, in terms of choosing and prioritising what is relatively more sustainable than other materials.

The choice of materials should be included when assessing which material is relatively more sustainable than other materials. The hierarchy of materials shown in Figure can be used to indicate the range of the environmental impact. The higher the packaging is in the hierarchy, the lower its environmental impact. As such, the hierarchy of materials can provide an overview of whether there is room for improvement in terms of choice of material.

The hierarchy of materials does not include information about the specific weight or the degree of recyclability. Therefore, the decision on which measures to take to reduce the environmental impact should not be based on the hierarchy of materials alone. The degree of recyclability and the specific weight of the different packaging materials should also be included in the assessment. Also Appendix G about the European Packaging and Packaging Waste Directive.

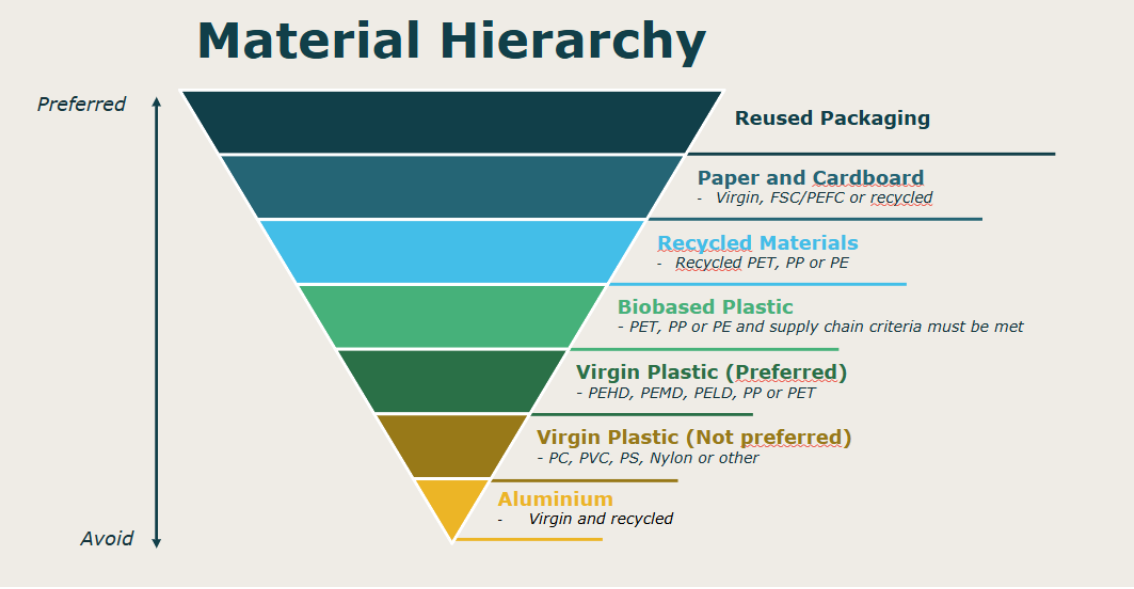


Figure 2 Hierarchy of materials for choosing which materials are preferable to others. Note biogenic plastic here represent bioplastics from first and partly secondary raw materials.

3 Guide to the use of the criteria

This document includes:

- a library of criteria, which is included in chapter 4
- a glossary and abbreviations, which are included in Appendix A and Appendix B
- elaborations on definitions, standards, directives and ancillary tools for the tender process, which are included in Appendix C to H.

For each of the three sustainability topics, a library of criteria is presented. The criteria include the main materials that are traditionally used for packaging, i.e., plastics, cardboard and metals.

The criteria are divided into three levels according to their potential climate and environmental impact:

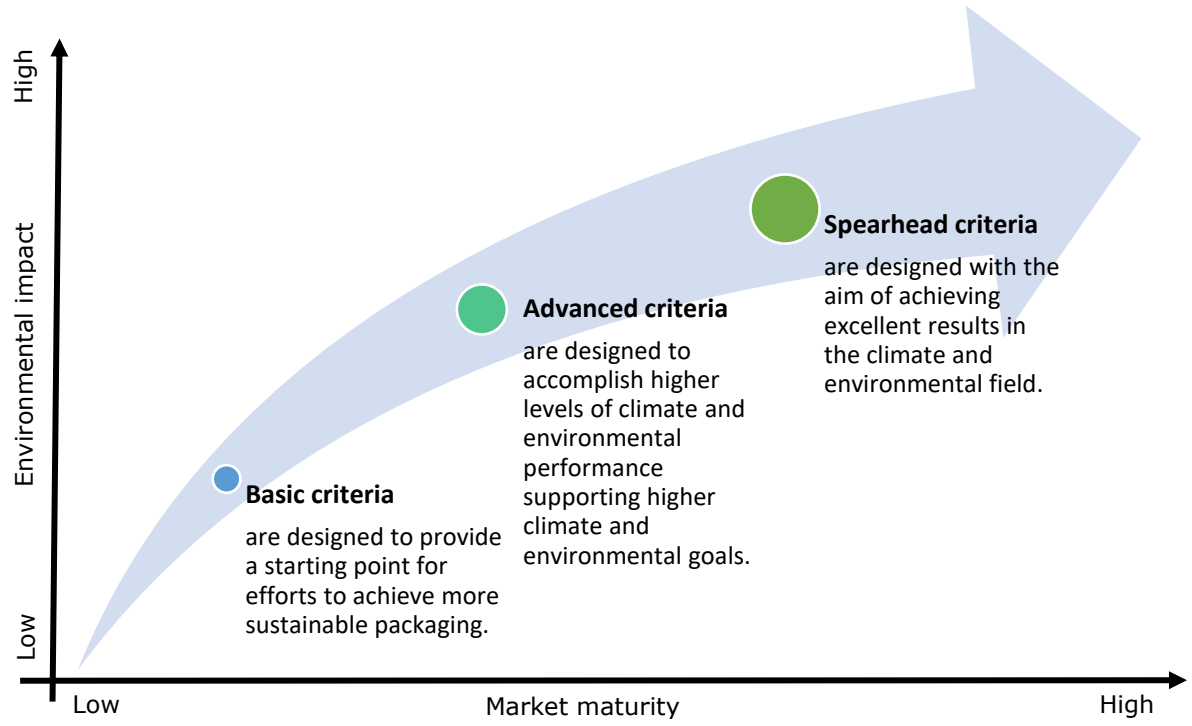


Figure 3 Each packaging criterion is divided into three levels—Basic, Advanced, and Frontrunner. The levels have different environmental impacts, and the choice between them depends on the maturity of the market

The criteria are expected to be relevant to up to 80 per cent of all packaging. It is necessary that the feasibility of all criteria be tested through early market dialogue in the pre-tendering process. This will enable the adaption of the criteria to be in line with the market maturity of the individual product segment.

In some cases, aspects may challenge the use of the criteria due to, e.g., specific requirements for product packaging, such as sterile packaging, or requirements for storage etc. The use of the criteria should therefore be implemented accordingly.

The criteria are designed to be copied and applied directly; however, it may prove useful to adjust the text to the specific tender documents. The early market dialogue and the results of any consultation may determine whether a criterion should be used as a minimum requirement or a competition criterion in the specific tender process.

It is expected that the market will develop. As it does, the criteria will move up the ladder, i.e., advanced criteria are expected to be basic criteria in the coming years and spearhead criteria to be advanced criteria at some point. However, to push the market, it is important to use the criteria as often and as broadly as possible when purchasing products for the health sector.

The use of the criteria must not compromise requirements related to patient safety, product approval procedures or criteria in standards (e.g., ISO 11607 standard series, the Directive 93/42/EEC on Medical Devices, the Directive 90/385/EEC on Active Implantable Medical Devices, Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Regulation (EU) 2017/745 on Medical Devices, Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices).

3.1 Use of the criteria

This section explains when and how you can work with sustainability requirements for packaging in a typical tender process. Tender processes may differ in planning, so this section is based on a generic and simplified tender process that usually consists of the following phases:

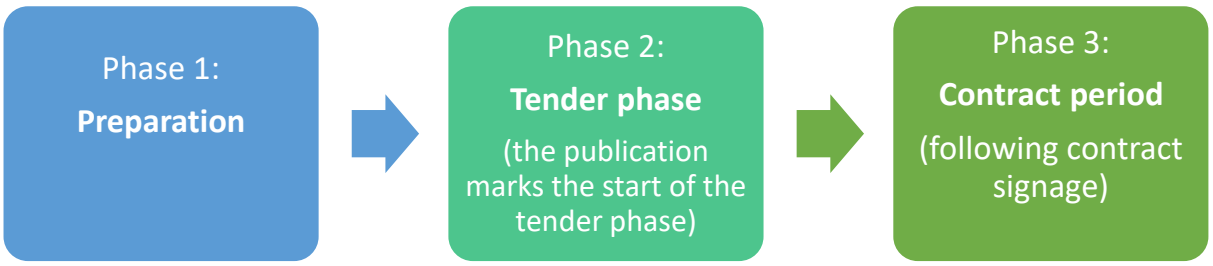


Figure 4 The phases in a generic and simplified procurement process

Phase 1 – Preparation

The preparation includes all activities carried out before the call for tenders is ready for publication and is the most important phase in terms of building sufficient knowledge about the specific packaging so as to include relevant requirements in the tender documents.

Figure 5 – Phase 1, Preparation consists of many sub-elements and considerations, as illustrated in the figure. First analysis, then market dialogue, and finally selection of criteria

The level of ambition is increased by:

1. Applying a higher level of criteria,
2. Using the criteria as minimum requirements

3. And by giving a higher weight to climate and environment-related competition criteria in the tender

Phase 2 – Tender phase

The tender phase starts with the publication of the call for tenders. In this phase, focus is on:

1. answering any questions regarding the criteria following publication, while complying with the principles of tender law.
2. evaluating the tender process.

Phase 3 – Contract period

In the contract period, parties may be invited to dialogues about results, processes and the results of any agreed development activities, for instance once a year, and follow up on compliance with the stated criteria. If the supplier is required to make improvements or work with specific plans during the contract period, this must be followed up on – the contract must state how and how often you want to follow up on such measures.

Innovation clauses can create the flexibility and collaboration that makes it possible to realize spearhead criteria in practice – even if the market is not yet completely ready at the start of the contract. In other words, the contract terms help set a clear direction for what the contracting authority wants to promote – and can act as leverage for manufacturers and suppliers who are already working with sustainable packaging.

Innovation clauses can play an important role when contract terms are ahead of the current market. Instead of excluding suppliers who are almost there, innovation clauses allow for:

- Develop and test new packaging types in collaboration between the client and supplier
- Implement packaging improvements in stages during the contract period
- Reward documented improvements in the environmental profile of packaging
- Adapt solutions continuously in line with technological advances

When contract terms and innovation clauses are used together, it enables a progressive approach to packaging criteria in tenders:

- Contract terms communicate that the contracting authority has high sustainability ambitions – and wants to reward the suppliers who are furthest along
- The innovation clauses create the opportunity for suppliers who cannot yet meet the requirements at the start of the contract to commit to a development plan that leads to fulfillment

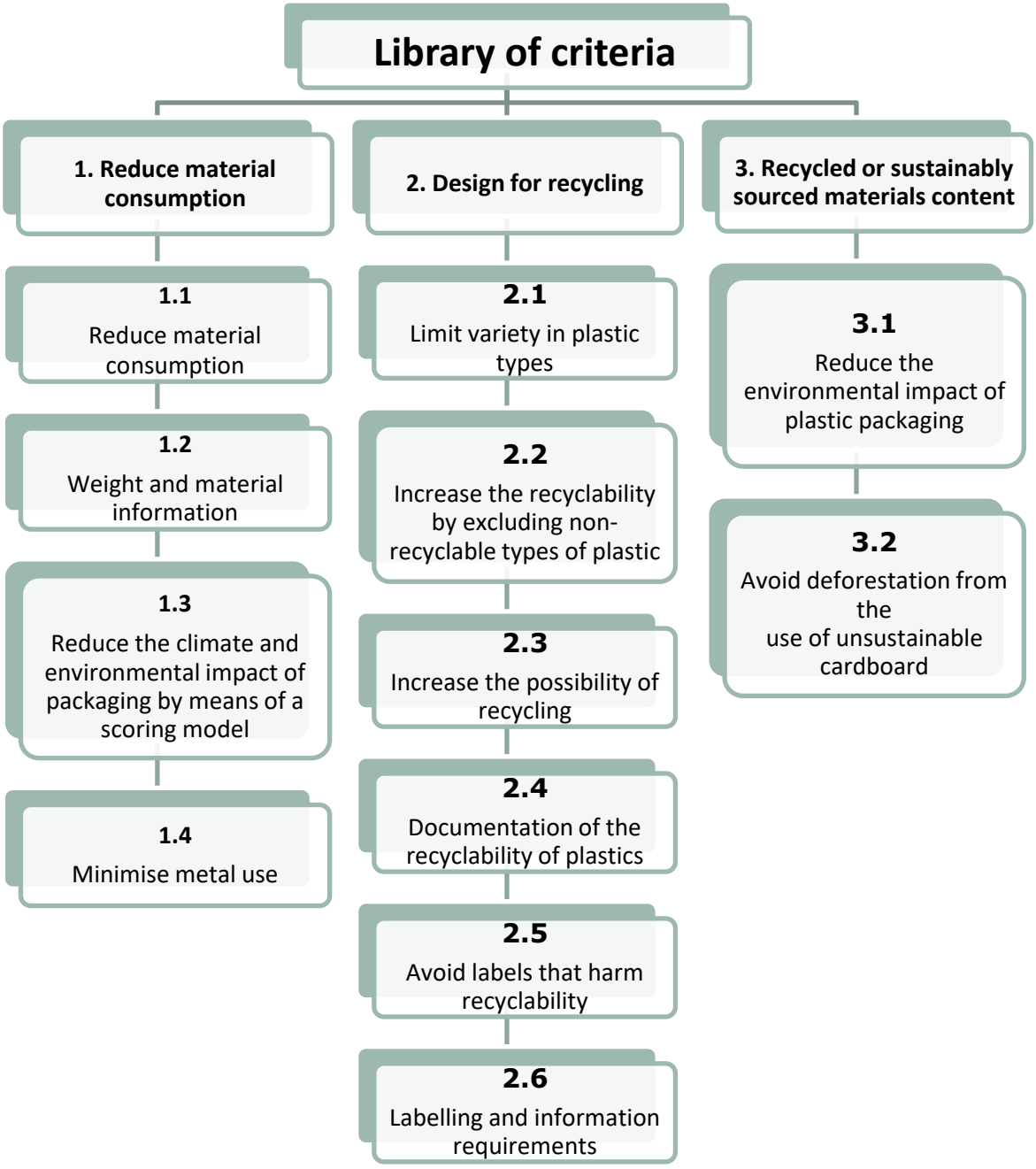
In this way, both competition and development are supported, while the market receives a clear signal about which direction to take.

4 Library of criteria

The criteria are divided into three sections according to their sustainability purpose:

1. Reduce material consumption
2. Design for recycling
3. Recycled or sustainably sourced materials content.

If the criteria compromise current safety, legal, regulatory or standard requirements for a specific product, they must be adjusted to avoid compromising safety, legal, regulatory or standard requirements.



4.1 Reduce material consumption

The aim of the following criteria is to reduce and minimise materials used for packaging and promote more sustainable choices of materials. As a result of the most recent amendments to the EU Regulation (EU) 2021/2226, which entered into force on 16 July 2025, it is now lawful to provide electronic instruction for use instead of a physical paper version, including products covered by MDR Annex XVI. This new option constitutes a significant contribution to reducing material consumption.

The option to provide instructions for use in electronic form has an impact on criteria 1.2 and 1.3, where the total weight of the packaging – including the instructions for use – is assessed positively.

There are four types of requirements that make it possible to set requirements for reduced material consumption.

Only choose one of either criteria 1.1, 1.2 or 1.3 to avoid evaluating the same type of information in different ways.

In the market dialogue, clarify whether 1.4 (metal in packaging) is relevant for the products in the specific call for tenders.

Criterion 1.1.: Reduce material consumption

The advantage of using this criterion is that reference is made to an international standard that is relatively well-known. Evaluating on the criterion is simple. The standard is described in brief in Appendix F.

No.	Level	Criteria	Documentation
1.1 *Reduce material consumption*	***Basic***	**Competition criterion** It is considered positive that, at contract start, the proposed packaging has been minimised in terms of weight and volume in the last 5 years in accordance with the ten performance criteria in EN 13428 or similar.	Completion of Annex A in EN 13428, stating which of the ten performance criteria are met.
	Advanced	**Minimum requirement** At contract start, the proposed packaging must be minimised in terms of weight and volume in the last 5 years in accordance with the ten performance criteria in EN 13428 or similar.	Declaration of conformity with EN 13428.
	Spearhead	-	-

Criterion 1.2. Weight and material information

The advantage of applying this criterion is that the response provides a solid data basis, including calculating the total weight of a given packaging. This information can be useful, particularly when working to reduce waste volumes. The combination of data on weight and material also provides a strong basis for calculating the CO_2e footprint of the specific amount of packaging.

No.	Level	Criteria	Documentation
1.2 *Weight and material information*	***Basic***	**Competition requirements** It is weighed positively that packaging has the lowest possible weight and the most sustainable materials possible are used For the five products that make up the largest quantity (by weight) in the tender list, please state the specific weight in grams and the material type for all packaging (primary, secondary and tertiary packaging, including filling material and, where applicable, instructions for use). The winning tender must submit data sheets for the five products.	*The weight in grams and types of material used for all packaging (primary, secondary and tertiary packaging, including filling material and, where applicable, instructions for use) are stated in the bill of quantities. As for plastics (LDPE, HDPE, LLDPE, PP, PET etc.), the main type must be stated in grams and in percentage of recycled or bio-based content.*
	Advanced	**Minimum requirement** State the specific weight and the types of material used for all packaging (primary, secondary, tertiary packaging, including filling material, and, where applicable, instructions for use). The winning tenderer must submit data sheets for every product in the bill of quantities.	*The weight in grams and types of material used for all packaging (primary, secondary, tertiary packaging, including filling material, and, where applicable, instructions for use) are stated in the bill of quantities. As for plastics (LDPE, HDPE, LLDPE, PP, PET etc.), the main type must be stated in grams and in percentage of recycled or bio-based content.*
	Spearhead	-	-

Criterion 1.3 Reduce the climate and environmental impact of packaging by means of a scoring model

The advantage of using this criterion is that the supplier can provide data in a simple and uniform manner that is comparable across suppliers. The scoring model calculates the total climate and environmental impact of the specific packaging as one single score.

The scoring model is designed to automatically favour use of the most sustainable materials.

The scoring model consists of a spreadsheet complete with a user guide, as well as an elaborative description of method, which transparently accounts for the decisions that the scoring model is built on. See Appendix D for an introduction to the scoring model and the actual scoring model in the Excel file 'Environmental factor scoring calculation'.

To ensure that all offers are evaluated consistently in relation to one another, interpolation is used when awarding points. Interpolation means that a proportional intermediate value is calculated between two known values. The interpolation calculates the points proportionally based on the scores of the offers, such that the lowest score is awarded the best points, and the remaining scores are converted proportionally in relation thereto. Below is an example where the best points are 8 and the worst points are 0.

Interpolation formula:

$$Offer\ points = Best\ points + \frac{Offer\ score - Lowest\ score}{Highest\ score - Lowest\ score}\ x\ (Worst\ points - Best\ points)$$

- **Offer points**: The points that the offer receives in the evaluation
- **Offer score**: The score calculated in the scoring model
- **Highest score**: The offer score that is the highest in the tender
- **Lowest score**: The offer score that is the lowest in the tender
- **Best points**: The points that are best on the evaluation scale, e.g. 8 or 0
- **Worst points**: The points that are worst on the evaluation scale, e.g. 0 or 8

Table 1: Example of points calculation

Supplier	**Offer score**	**Example of calculation (Best point is 8)**	**Offer points (Best point is 8)**	**Example of calculation (Best point is 0)**	**Offer points (Best point is 0)**
A	63.9	$8 + \left(\frac{63.9 - 4.7}{109.4 - 4.7}\right) \cdot (0 - 8) = 3$	3	$0 + \left(\frac{63.9 - 4.7}{109.4 - 4.7}\right) \cdot (8 - 0) = 5$	5
B	20.3	$8 + \left(\frac{63.9 - 4.7}{109.4 - 4.7}\right) \cdot (0 - 8) = 7$	7	$0 + \left(\frac{20.3 - 4.7}{109.4 - 4.7}\right) \cdot (8 - 0) = 1$	1
C	109.4	$8 + \left(\frac{109.4 - 4.7}{109.4 - 4.7}\right) \cdot (0 - 8) = 0$	0	$8 + \left(\frac{109.4 - 4.7}{109.4 - 4.7}\right) \cdot (8 - 0) = 8$	8
D	4.7	$8 + \left(\frac{4.7 - 4.7}{109.4 - 4.7}\right) \cdot (0 - 8) = 8$	8	$8 + \left(\frac{4.7 - 4.7}{109.4 - 4.7}\right) \cdot (8 - 0) = 0$	0

No.	Level	Criteria	Documentation
1.3 *Reduce the climate and environmental impact of packaging*	***Basic***	**Competition criterion** The purpose of this criterion is to reduce the environmental and climate impact of packaging through the use of a scoring model. The lower the score achieved by a tender, the better points are awarded in the evaluation of the tender. Points are calculated by linear interpolation between the lowest and the highest total score in the Tender Annex "Scoring model for packaging", such that the tender with the lowest score receives the best points, and the tender with the highest score receives the worst. Other tenders are awarded points proportionally between these two extremes. The tenderer/supplier must complete the Tender Annex "Scoring model for packaging" in the worksheet titled "Scoring model". Instructions on how to complete the "Scoring model" worksheet are provided in the worksheet titled "Introduction". The tenderer/supplier must attach the completed Tender Annex to the tender. A points-based model is applied, whereby the total calculation in the Tender Annex is converted into an "overall score" (shown in cell M10). Documentation must be submitted upon request. The contracting authority reserves the right to test the result based on the weight and material types stated in the "Scoring model" worksheet.	*Filled-in calculation from the scoring model.* *No further documentation is required.* *The contracting authority reserves the right to test the result based on the specified weight and types of material stated in the bills of quantities.* *The tenderer must complete the Tender Annex "Environmental factor scoring model for packaging" for the product in question.* *In addition, the tenderer/supplier must attach the completed calculation from Sub-Annex [XX] to the specification of requirements Scoring model for packaging.* *Documentation must be submitted upon request.*
	Advanced	-	-
	Spearhead	-	-

Criterion 1.4: Minimise metal use

The advantage of using this criterion is that it can be used to phase out packaging with metal, e.g., aluminium such as aluminium film on the inside of plastic bags, to prevent inexpedient substitution that increases the consumption of aluminium packaging.

The criteria permit nails and staples as well as metal layers serving as barriers, e.g., small barrier capsules in bottles with liquid content.

No.	Level	Criteria	Documentation
1.4 *Minimise metal use*	***Basic***	**Minimum requirement** No metal can be utilised in secondary or tertiary packaging, with the exception of nails in pallets and staples in cardboard boxes.	*Declaration of conformity (See Appendix H for the content of the Declaration of Conformity)*
	Advanced	**Minimum requirement** No metal can be utilised in secondary or tertiary packaging, with the exception of nails in pallets and staples in cardboard boxes. No metal can be utilised in primary packaging, with the exception of metal layers serving as barriers that are thinner than 5 µm and placed on the inside or middle layer of flexible plastic packaging.	*Declaration of conformity (See Appendix H for the content of the Declaration of Conformity)*
	Spearhead	-	-

4.2 Design for recycling of plastics

The intention of Regulation 2025/40 is, among other things, to contribute to ensuring that all packaging placed on the market in the EU is recyclable or reusable by 2030[4]. Plastic packaging for the healthcare sector is often of very high material quality. Furthermore, the effect of recycling plastic in relation to CO_2e emissions is five times higher compared to energy utilisation. There is therefore good reason to organise the recycling of as much plastic packaging from the healthcare sector as possible. There are two central principles in particular in Regulation 2025/40 that are intended to contribute to increased recycling:

1. Packaging is considered recyclable if it meets the following conditions:

a) It is designed for material recycling, which enables the use of the resulting secondary raw materials that are of sufficient quality compared to the original material to be used to replace primary raw materials.

b) When it becomes waste, it can be collected separately, sorted into specific waste streams without affecting the recyclability of other waste streams, and recycled on a large scale.[5]

2. The recyclability of packaging must be assessed on the basis of performance classes.

From 1 January 2030, all packaging must have a performance class in relation to recyclability of A, B or C. The Commission is expected to define these performance classes in delegated acts by 1 January 2028. Packaging with a recyclability below 70% is, from 2030, considered non-recyclable under Regulation 2025/40.

With the Packaging Criteria, good experience has been gained since 2022 in applying the principle of performance classes for recyclability, e.g. from the RecyClass self-assessment online tool in (Spearhead criterion 2.4). Until the EU Commission has published new definitions of performance classes, packaging criterion 2.4 will be used where relevant, based on RecyClass or similar.

To ensure transparency about the recyclability of packaging, manufacturers should use QR codes or other digital data carriers. These can provide consumers with access to detailed information about the packaging's composition, sorting instructions and producer responsibility measures.

Certain types of packaging for medical devices and pharmaceuticals are exempt from the recyclability requirement in Regulation 2025/40:

- Primary packaging
- Contact-sensitive[6] packaging for medical devices
- Contact-sensitive packaging for in-vitro diagnostics
- Packaging that is necessary for the quality of a medicine

[4] Regulation 2025/40), Preamble recital (5)
[5] Regulation 2025/40, Article 6(2)(a) and (b).
[6] Contact-sensitive packaging refers to packaging where there may be a risk of diffusion from the packaging into the product.

- Contact-sensitive packaging for infant formula and other nutritional supplements used for medical purposes[7]

Extended producer responsibility has been established for all types of packaging in the EU/EEA. The purpose of producer responsibility is to promote recycling with the incentive that the easier it is to recycle packaging, the cheaper it will be for companies. Under this, effective and economically sustainable recycling schemes have been established for the most common types of plastic - such as PE (LDPE, HDPE, LLDPE), PP and PET.

According to the regulation's definition of actual material recycling, this means that other types of plastic than the most commonly used and actually recyclable ones, such as those mentioned above, are not necessarily actually recyclable, even if they are technically recyclable in isolation. When other and possibly quantitatively marginal types of plastic enter a total waste stream, they will contribute to 'polluting' the mainstream of recyclable plastic, thereby reducing the quality of the material recycling.

By contaminating the main streams for plastic recycling, the types of plastic other than the most commonly used recyclable plastic types will contribute to making plastic recycling less economically viable. Therefore, the requirements in the Packaging Criteria contribute to reducing the complexity of the material flow from packaging to the healthcare sector by phasing out those types of plastic that are less actually recyclable than the main streams for plastic recycling. In the Packaging Criteria, this is translated into a positive list of desired materials (packaging criterion 2.1) and a negative list of undesirable materials (packaging criterion 2.2).

Packaging must be designed to minimise the presence of substances of concern, both for the sake of human health and the environment, and to increase opportunities for recycling and reuse of packaging. The Commission will draw up a list of substances of concern in packaging by 31 December 2026 and decide which ones have a negative impact on people and the environment.

In packaging criteria, the phasing out of already known problematic substance groups is supported through a new requirement focusing on the phasing out of the following substances and substance groups:

- PFAS
- BPA
- Lead
- Cadmium
- Mercury and
- Hexavalent Chromium[8]

A particular challenge in relation to the recycling of plastic packaging in the healthcare sector is the use of labels made of a material other than the main component of the packaging, such as paper labels. Paper labels significantly reduce the quality of the recycled plastic and also significantly reduce the economic profitability of the recycling process.

[7] Regulation 2025/40, Article 7(4).

[8] Regulation 2025/40, Article 6, paragraphs 4 and 5

Six criteria have been proposed to increase the recyclability of plastics. The six criteria complement each other and can therefore all be used in the same tender.

Criterion 2.1. Limit variety in plastic types

The advantage of using criterion 2.1. is to promote plastic types (polyolefins and PET primarily) for which there are effective recycling streams. The criterion can be seen as a positive list.

No.	Level	Criteria	Documentation
2.1 *Limit variety in plastic types*	***Basic***	**Minimum requirement** If the tertiary packaging is plastic, then PE (LDPE, HDPE, LLDPE), PP or transparent PET must be used for the main component (more than 95 per cent of the total weight of the packaging). If the tertiary packaging is not plastic, this requirement does not apply.	*Declaration of conformity which states that the specific packaging meets the criterion.*
	Advanced	**Minimum requirement** If the tertiary and/or the secondary packaging is plastic, then PE (LDPE, HDPE, LLDPE), PP or transparent PET must be used for the main component (more than 95 per cent of the total weight of the packaging). If the tertiary and/or secondary packaging is not plastic, this requirement does not apply.	*Declaration of conformity which states that the specific packaging meets the criterion.*
	Spearhead	**Minimum requirement** If the packaging is plastic, then PE (LDPE, HDPE, LLDPE), PP or transparent PET must be used for the main component (more than 95 per cent of the total weight of the packaging). If the packaging is not plastic, this requirement does not apply.	*Declaration of conformity which states that the specific packaging meets the criterion.*

All three levels of this criterion are stated as minimum requirements. Therefore, it is important, through dialogue with the suppliers, that a sufficient number of suppliers are able to meet the requirements. The criterion may be considered a positive list of permitted materials

Criterion 2.2. Increase the recyclability by excluding non-recyclable types of plastic

The advantage of this criterion is that criterion 2.2. mentions the types of plastic that cannot be included in plastic waste streams without reducing the quality of recycling and/or increasing the cost of waste treatment. Criterion 2.2. can be seen as a negative list.

The materials may be recyclable in isolation. Today, the materials mentioned in criterion 2.2. are either present in such small quantities that it is not profitable to collect them separately and/or they have a chemical composition that, in an overall packaging waste stream, affects the recyclability of other waste streams.

It is possible to use the criterion as a competitive criterion if the market is not ready for a minimum requirement. In that case, it is recommended to combine it with a requirement in the contract that materials on the 'negative list' must be phased out within the term of the contract.

If necessary, use criteria 2.1 and 2.2. together.

No.	Level	Criteria	Documentation
2.2 Increase recyclability	***Basic***	**Minimum requirement** The plastic packaging cannot be made of: › Styrene polymers (PS, EPS, XPS) › Regenerated cellulose (e.g., cellophane) › Biodegradable polymers, including polymers that are compostable[9]. Secondary and tertiary packaging cannot be made of: › PVC › Composite and/or packaging combining different materials, (e.g., cardboard with plastic window). If the packaging is not plastic, this requirement does not apply	*Provide a technical data sheet which describes the material composition of the packaging.*
	Advanced	**Minimum requirement** The plastic packaging cannot be made of: › Styrene polymers (PS, EPS, XPS) › Regenerated cellulose (e.g., cellophane) › Biodegradable polymers, including polymers that are compostable › PVC Primary, secondary and tertiary packaging cannot be made of: › Composite and/or packaging combining different materials, (e.g., cardboard with plastic window). If the packaging is not plastic, this requirement does not apply.	*Provide a technical data sheet which describes the material composition of the packaging*

[9] Please note that oxo-degradable plastic is no longer permitted according to EU Directive 2019/904.

	Spearhead	**Minimum requirement** Primary, secondary, and tertiary packaging, as well as filling material, must be made of PE (LDPE, HDPE, LLDPE), PP, or PET, of which at least 70% must be biobased plastic. Biobased plastic must have a certified supply chain. If the packaging and/or filling material is not plastic, this requirement does not apply.	*Provide a technical data sheet which describes the material composition of the packaging*. A certified supply chain can be documented through relevant certification such as ISCC PLUS, RSB, Bonsucro, or similar schemes. *Other relevant schemes are listed on the EU's list of EU RED III-approved voluntary schemes:* *https://energy.ec.europa.eu/topics/renewable-energy/bioenergy/voluntary-schemes_en#related-links*

Criterion 2.3 Increase the possibility of recycling

Packaging must be designed to minimise the presence of substances of concern, both for the sake of human health and the environment, and in connection with the recycling and reuse of packaging. The Commission will draw up a list of substances of concern in packaging by December 31st, 2026, and decide which ones have a negative impact on people and the environment.

The packaging criteria support the phasing out of already known problematic substance groups through a new requirement focusing on the phasing out of the following substances and substance groups:

- PFAS
- BPA
- Lead
- Cadmium
- Mercury and
- Hexavalent Chromium[10]

[10] Regulation 2025/40, Article 6, paragraphs 4 and 5

No.	Level	Criteria	Documentation
2.3 Increase the possibility of recycling	***Basic***	-	
	Advanced	-	
	Spearhead	**Competition criterion** It is considered positive that the packaging does not contain the following problematic substances that have a negative effect on the reuse and recycling of packaging: • PFAS • BPA • Lead • Cadmium • Mercury and • Hexavalent Chrom If the packaging does not contain any of these problematic substances, the highest score is awarded.	*Declaration of conformity, which declares that the specific packaging complies with the criterion (see Appendix H for content of the declaration of conformity).*

Criterion 2.4. Documentation of the recyclability of plastics

Regulation 2025/40 stipulates that the performance of packaging in relation to recyclability must be documented and expressed by grades A, B or C. Packaging with a recyclability below 70% is, from 2030, considered non-recyclable under Regulation 2025/40.

In the packaging criteria, this method for documenting recyclability has been used with good experience, based on an online tool developed by the European trade organization of plastic recyclers, Plastic Recyclers Europe. The documentation tool consists of a third party-operated European online tool, called 'RecyClass'. The tool provides easy access to a free assessment of the recyclability of plastic packaging. The assessment indicates the recyclability of plastic packaging with a letter, in the same way as it is known from energy labeling. The letters can easily be converted into a score.

Using this method requires that the tenderer has full knowledge of the packaging and its components, as otherwise the tool cannot be completed accurately.

When entering a contract, the winning supplier(s) must be requested to provide actual certification of the recyclability of their packaging.

In addition, RecyClass also provides a justification for the score obtained for the recyclability of the specific packaging and thus provides the bidder with instructions on possible improvement opportunities.

When the Commission develops delegated acts by 1 January 2028 setting out criteria for defining performance classes for recyclability, the Packaging Criteria will follow these.

No.	Level	Criteria	Documentation
2.4 *Document recyclability*	***Basic***	-	-
	Advanced	**Competition criterion** It is considered positive to which extent the recyclability of the plastic packaging is documented by means of a free self-assessment by RecyClass or a similar certification scheme. The higher the score (class), the more points are given in the evaluation of the tender. The winning tenderer must present an actual certification, at no cost to the contracting authority. If the packaging is made of cardboard, paper or a similar fibre-based material, the maximum number of points are granted.	*State certification of class from RecyClass or the like (e.g., Cyclos-HTP).*
	Spearhead	**Minimum requirement** If the packaging is plastic, the recyclability of plastic packaging(s) must be documented by means of certification by RecyClass or a similar certification scheme. Plastic packaging must, as a minimum, meet the requirements for Class B in RecyClass or similar level in other certification system. If the packaging is not plastic, this requirement does not apply.	*Present certification by RecyClass documenting class A or B or a similar level (e.g., Cyclos-HTP) in a similar certification scheme.*

Criterion 2.5. Labels that do not harm the recyclability of plastic packaging

The benefit of this criterion is to avoid labels that reduce the possibility of recycling plastic. Many paper-based labels and adhesives make it more difficult to recycle plastic packaging because the paper reduces the quality and value of the plastic.

The best thing is to avoid labels altogether by, for example, printing necessary information directly on the packaging where possible, without compromising safety and documentation.

However, the healthcare sector is subject to strict requirements regarding safety and documentation. This often means that essential information must be stated directly on the products, for example, on labels. Some products must withstand exposure to hot water for up to 48 hours, which place specific requirements on both the label material and the adhesive. For products with such requirements, it is recommended, where possible, to avoid setting requirements for the label.

Please note that this does not apply to primary and secondary packaging for medical devices, diagnostic equipment or medicines if there is no space for additional labelling due to traceability, safety and product information requirements – or if additional labelling could make the use of the device less safe.

No.	Level	Criteria	Documentation
2.5 *Avoid labels that harm recyclability*	***Basic***	**Competition criterion** It is considered positive to what extent labels on plastic packaging comply with the following options: › It must be possible to wash off labels at temperatures below 60 °C and be water soluble/releasable. › Labels must be made of the same material as the packaging. › If the packaging is PET, the label must be PP or PE (LDPE, HDPE, LLDPE) and not cover more than 40 per cent of the surface. If the packaging does not feature a label, the maximum number of points are granted.	*State which options the packaging complies with.*
	Advanced	**Minimum requirement** Labels on plastic packaging must comply with *at least* one of the following options: › It must be possible to wash off labels at temperatures below 60 °C and be water soluble/releasable. › Labels must be made of the same material as the packaging. › If the packaging is PET, the label must be PP or PE (LDPE, HDPE, LLDPE) and not cover more than 40 per cent of the surface. If the packaging does not feature a label, this requirement does not apply.	*State which options the packaging complies with.*
	Spearhead	**Competition criterion** It is considered positive that labels on plastic packaging wash off at temperatures below 60 °C and are water soluble. If the packaging does not feature a label, the maximum number of points are granted.	-

Criterion 2.6. Labelling and information requirements

Packaging may be provided with a harmonised label indicating the material composition to facilitate sorting by consumers. The label must be pictogram-based and easy to understand. The packaging label should also provide information on correct disposal.

Packaging containing problematic substances must be digitally labelled using standardized technologies such as a QR code or other digital data carriers.

No.	Level	Criteria	Documentation
2.6 *Labelling and information requirements*	***Basic***	-	-
	Advanced	-	-
	Spearhead	**Competition criterion** It is considered positive that the packaging is provided with a QR code that contains information about problematic substances, material composition and correct disposal.	*The supplier must provide documentation showing an active QR code or other digital data carrier where the information appears.*

4.3 Recycled or sustainably sourced materials content

The aim of the following criteria is to promote the use of recycled materials and sustainably sourced materials. By requiring that packaging contains a certain percentage of recycled materials, the total climate and environmental impact is reduced since no energy or materials are used on procuring virgin materials.

However, the use of recycled materials presumes that the materials are clean and, e.g., do not contain any unwanted and harmful substances that may accumulate in the environment and people through the recycling process.

The two suggested criteria apply to plastic- and fibre-based packaging, respectively. The total packaging may contain both plastic- and fibre-based packaging (e.g., the primary packaging may be a plastic bag, and the secondary packaging may be a cardboard box). Therefore, both criteria may be used in tender documents, just targeting different packaging materials.

Criterion 3.1. Reduce the climate and environmental impact of plastic packaging

The criterion aims to reduce the climate and environmental impact of plastic packaging by requesting recycled resources and sustainably sourced materials. By having recycled plastic make up a certain percentage of the packaging, you go from virgin fossil-based materials to materials that do not put any pressure on non-renewable materials.

By having bio-based plastic make up a certain percentage, you go from fossil-based materials to renewable materials. For this to become a true advantage, the bio-based plastic is presumed to come from certified sources and be either 2nd or 3rd generation bioplastic. This means that the bio-based plastic materials are not made of materials, or from land area, that could have been used for food and crops. Instead, the plastic is made of by-products from food production or waste, such as sugar canes or bio-waste.

No.	Level	Criteria	Documentation
3.1 Reduce the environmental impact of plastic packaging	***Basic***	-	-
	Advanced	**Minimum requirement** If the tertiary packaging includes plastic: At least 50 per cent of the plastic content of th tertiary packaging is made of recycled plastic or bio-based plastic[1] Bio-based must be PE (LDPE, HDPE, LLDPE), PP, PET and have a certified chain of suppliers (e.g., RSB, Bonsucro or the like) or be 2nd or 3rd generation bio-plastic. If the tertiary packaging is not plastic, this requirement does not apply.	*No documentation is required in the tender.* *Prior to contact signing, documentation must be presented. The documentation must be provided in accordance with ASTM D6866, EN16785-1 or similar for bio-based content and/or EN15343, ISO 22095 or similar for recycled content.*
	Spearhead	**Minimum requirement** If the tertiary and/or secondary packaging includes plastic: At least 50 per cent of the plastic content of the secondary and the tertiary packaging is made of from recycled plastic or biobased plastic[1] Bio-based must be PE (LDPE, HDPE, LLDPE), PP, PET and have a certified chain of suppliers (e.g., RSB, Bonsucro or the like) or be 2nd or 3rd generation bio-plastic. *If the tertiary and/or secondary packaging is not plastic, this requirement does not apply.*	*No documentation is required in the tender.* *Prior to contact signing, documentation must be presented. The documentation must be provided in accordance with ASTM D6866, EN16785-1 or similar for bio-based content and/or EN15343, ISO 22095 or similar for recycled content.* *A certified supply chain can be documented with relevant certifications such as ISCC PLUS, RSB, Bonsucro or similar. Other relevant certification schemes can be found on the EU's list of EU RED III approved voluntary schemes: https://energy.ec.europa.eu/topics/renewable-energy/bioenergy/voluntary-schemes_en#related-links*

Criterion 3.2. Reduce the climate and environmental impact of fibre-based materials

By requesting fibre-based packaging (e.g., cardboard or paper) that contains a certain percentage of recycled fibres, the climate and environmental impact is reduced since fewer virgin materials are extracted. By requesting fibre-based packaging made entirely or partly by FSC- or PEFC-certified wood and fibre products, it is ensured that the fibres come from forests managed sustainably in relation to both the environment and people.

No.	Level	Criteria	Documentation
3.2 *Avoid de-forestation from the use of un-sustainable cardboard*	***Basic***	**Minimum requirement** If the tertiary and/or secondary packaging is fibre-based: At least 50 per cent FSC/PEFC-certified (or otherwise certified sustainably sourced) or recycled fibres. If the tertiary and/or secondary packaging is not fibre-based, this requirement does not apply.	*Declaration of conformity (See appendix H for the content of the declaration of conformity)* *A copy of the certificate, as well as an invoice/delivery note or data sheet containing the supplier's Chain of Custody code and an FSC/PEFC/or equivalent scheme claim on the product line or in clear association with the certificate.*
	Advanced	**Minimum requirement** If the tertiary and/or secondary packaging and/or manual/leaflet is fibre-based: At least 90 per cent FSC/PEFC-certified (or otherwise certified sustainably sourced) or recycled fibres. If the tertiary and/or secondary packaging and/or manual/leaflet is not fibre-based, this requirement does not apply.	*Declaration of conformity (See appendix H for the content of the declaration of conformity)* *A copy of the certificate, as well as an invoice/delivery note or data sheet containing the supplier's Chain of Custody code and an FSC/PEFC/or equivalent scheme claim on the product line or in clear association with the certificate.*
	Spearhead	**Minimum requirement** If the packaging and/or manual/leaflet is fibre-based: At least 90 per cent FSC/PEFC-certified (or otherwise certified sustainably sourced) or recycled fibres. If the packaging and/or manual/leaflet is not fibre-based, this requirement does not apply.	*Declaration of conformity (See appendix H for the content of the declaration of conformity)* *A copy of the certificate, as well as an invoice/delivery note or data sheet containing the supplier's Chain of Custody code and an FSC/PEFC/or equivalent scheme claim on the product line or in clear association with the certificate.*

5 Appendix

Appendix A Glossary

Documentation	
Declaration of Conformity	A written declaration from the manufacturer confirming that the packaging meets the requirements. It is kept with the technical documentation and must be available to authorities for 5 years (disposable packaging) or 10 years (reusable packaging).
Labelling and information requirements	Labeling and information requirements are used to draw attention to problematic substances and to facilitate sorting for the consumer, via a QR code or another type of standardized open digital data carrier.
AB distributor	The item is sent from a distributor.
AB factory	The item is shipped from a manufacturer.
Packaging	
Primary packaging	"sales packaging or primary packaging, i.e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase"[11]
Secondary packaging	"grouped packaging or secondary packaging, i.e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics"[12] (European Parliament and Council Directive 94/62/EC of 20 December 1994, article 3, paragraph 1). See further in Appendix C – about levels of packaging.
Tertiary packaging	Transport packaging or tertiary packaging, i.e. packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packaging in order to prevent physical handling and transport damage. Transport

[11] Regulation 2025/40, Article 3, paragraph 1, points 4 and 5

[12] Regulation 2025/40, Article 3, paragraph 1, point 6

	packaging does not include road, rail, ship and air containers;"[13]
User manuals	A physical paper instruction manual is considered part of the packaging. Following the latest amendments to EU Regulation (EU) 2021/2226, which entered into force on 16 July 2025, it is now permitted to provide electronic instructions for use instead of a physical paper version, including for products covered by MDR Annex XVI.
Fibre-based materials	
Fibre-based materials	Fibre-based materials are understood to be wood-based materials. This includes paper, paperboard, cardboard, wood, and other cellulose-based materials.
Regenerated cellulose	A class of materials produced by converting natural cellulose into a soluble cellulose derivative followed by regeneration, typically resulting in either a fibre (e.g. rayon) or a film (e.g. cellophane).
FSC	The Forest Stewardship Council (FSC) forest management certification confirms that forests are managed in a way that preserves biological diversity and benefits local communities and the working conditions of local employees, while also being economically viable. Several different FSC certifications exist, including FSC 100% (where all forest-based materials in the product/packaging originate from FSC-certified forests) and FSC MIX (where all forest-based materials in the product/packaging are made from one or more of the following sources: FSC-certified forests, controlled wood (FSC Controlled Wood), and recycled materials).
PEFC	The Programme for the Endorsement of Forest Certification (PEFC) is a forest management certification similar to FSC. PEFC works to promote and maintain responsible forest management practices. The difference between PEFC and FSC lies in the way the organisations are structured, as well as in the certification requirements and the control mechanisms.

[13] Regulation 2025/40, Article 3, paragraph 1, point 7

Filler material	
Empty space in packaging	Empty space in packaging means the difference between the total volume of multipack, transport, or e-commerce packaging and the volume of the sales packaging contained within it. Sharing of empty space in sales packaging means the difference between the total internal volume of the sales packaging and the volume of the packaged product. Spaces filled with filling materials such as paper strips, air cushions, bubble wrap, polystyrene loose fill, foam filling, wood wool, polystyrene, or Styrofoam are also considered empty space.
Filler material	Filler material may, for example, include paper strips, air cushions, bubble wrap, and wood wool.

Reuse and recycling	
Reuse	"'Reuse' shall mean any operation by which packaging, which has been conceived and designed to accomplish within its life cycle a minimum number of trips or rotations, is refilled or used for the same purpose for which it was conceived, with or without the support of auxiliary products present on the market enabling the packaging to be refilled; such reused packaging will become packaging waste when no longer subject to reuse"[14]
Recycling	"'Recycling' shall mean the reprocessing in a production process of the waste materials for the original purpose or for other purposes including organic recycling but excluding energy recovery"[15]
Recyclability	'Recyclability' is the ability of a material to reacquire the properties that it had in its virgin state, where virgin state refers to the material in its purest form before being processed or shaped for a specific use[16].
Open and closed recycling loops	'Closed-loop recycling' shall mean that the quality of the materials being recycled are kept at a similar level by cycling materials into the same application, whereas, an 'open-loop recycling' shall mean that the materials being recycled are degraded in quality and/or material properties, and require applications with lower demands (Ellen MacArthur Foundation, 2014, https://www.ellenmacarthurfoundation.org/assets/downloads/EllenMacArthurFoundation_TheNewPlasticsEconomy_20-1-16.pdf).
Disposal phase (incl. sorting and preparing for recycling)	The 'end of life' phase of a material or product, whether that is landfilling, incinerating, recycling or reusing.
Circular economy	'Circular economy' shall mean "an industrial system that is restorative and regenerative by design. It rests on three main principles: preserving and enhancing natural capital, optimising resource yields, and fostering system effectiveness" (Ellen MacArthur Foundation, 2014, https://www.ellenmacarthurfoundation.org/assets/downloads/EllenMacArthurFoundation_TheNewPlasticsEconomy_20-1-16.pdf).
Multilayer packaging, and Packaging combining	Multilayer packaging/packaging combining different materials consists of two or more materials, e.g., cardboard with a plastic window, or packaging with one side made of paper and the other made of plastic. It may be possible to manually separate some of these types of packaging consisting of several materials; however, since manual separation is not possible at hospitals, this type of packaging is typically unwanted. Packaging that can be separated in the recycling process is not considered

[14] Regulation 2025/40, Article 3, paragraph 1, point 27

[15] Regulation 2025/40, Article 3, paragraph 1, point 41

[16] Regulation 2025/40, Article 3, paragraph 1, point 38

different materials	multilayer packaging or packaging combining different materials. Among other things, that goes for labels and tape on cardboard boxes. Small labels and/or tape on packaging do not make packaging multilayer packaging.
Composite materials/packaging	Composite materials consist of two or more materials melted together without the possibility to mechanically separate them. E.g., reenforced packaging for sharp objects with nylon (PA) to ensure the products protection. They differ from the above (multilayer packaging and packaging combining different materials) in that the materials have been melted together and cannot be manually separated from each other. This type of packaging is typically not recyclable. Multilayer plastic packaging/composite plastic packaging is recyclable when the polymers are technically compactible, e.g., PE and PP.
Non-recyclable composite/ packaging	Non-recyclable composite are materials that will not separate before or in the recycling process.
Plastics	
Plastics/ polymers	A polymer is a chemical compound that contains a chain of repeating molecular units. A plastic material is a polymer, typically modified with additives, which can be moulded or shaped by pressure and temperature. See abbreviations below for different polymers and additives (e.g., to enhance barrier properties). See more on plastics and recycling hereof, e.g., in https://plastikviden.dk/media/212448/study-about-plastic-sorting-and-recycling.pdf
Bioplastic (bio-based and biodegradable)	A term that covers bio-based plastics, biodegradable plastics and plastics that is both bio-based and biodegradable. For further information, see, e.g.: https://www2.mst.dk/Udgiv/publications/2020/02/978-87-7038-165-9.pdf Bio-based plastics are plastics with building blocks that are derived partly or wholly from plant-based feedstocks. Bio-based plastic is categorised as first, second and third generation, depending on the origin of the bio-based feedstocks. First-generation bioplastic is made of edible feedstocks, second-generation bioplastic is made of agricultural and forestry residual products (non-food biomass), and third-generation bioplastic is made of bio-based waste products, e.g., used cooking oil).
Compostable plastics	Plastic that biodegrades in industrial composting facilities and is compliant with the standard EN 13432 (Packaging – Requirements for packaging recoverable through composting and biodegradation – Test scheme and evaluation criteria for the final acceptance of packaging).
Monomers	Monomers are the elements, that polymers consist of.

Bio-degradable (bio-degradation)	The breakdown of an organic chemical compound by micro-organisms into carbon dioxide, methane (in the absence of oxygen), water and mineral salts of any other elements present (mineralisation) and new biomass.
Mechanical recycling of plastics	Plastic waste is sorted and reprocessed by mechanical means (shredding, melting, granulation) into pellets, flakes, powders or granulates. Only thermoplastics goes through mechanical recycling. This is the most common form of recycling.
Chemical recycling of plastics	It is defined as techniques used to break down plastic polymers into their constituent monomers, which in turn can be used again in refineries, or petrochemical and chemical production. There are different types of chemical processes; examples are pyrolysis, hydrolysis, hydrocracking and gasification. In Europe, chemical recycling only recycles a small, but increasing share of packaging and post-consumer plastic waste. Also known as feedstock recycling.
Biological recycling of plastics	Biodegradable plastics that enters industrial composting facilities is said to be biologically recycled.
Technologically recyclable	'Technically recyclable' means that it is possible for a given material to be collected, sorted and transported to a recycling facility, and to be recycled into a 'new' product. That a material is technically recyclable only takes into consideration whether the material can be recycled, and not whether there is a demand for it on the market.
RecyClass	RecyClass is a tool where you in through a number of steps can check the level of recyclability of your package. There is also advice on improving your package's design and the possibility to get your package certified. Behind RecyClass is a collaboration across the value chain. See more at: https://recyclass.eu/
Cyclos HTP	Cyclos HTP is a German institute that certifies packaging and other goods as recyclable. See more at: https://www.cyclos-htp.de/
RSB	The Roundtable on Sustainable Biomaterials (RSB) is a global, multi-stakeholder independent organisation that drives the development of a bio-based and circular economy on a global scale through sustainability solutions, certification and collaborative partnerships. The RSB standard is a method of sustainability validation of bio-based and recycled resources. The RSB Standard is anchored in 12 sustainability principles, and their underlying criteria, to ensure that the key environmental and social issues surrounding the use of fuels and products made from bio-based and advanced feedstocks are addressed.

Bonsucro	Bonsucro – sustainability certification for sugarcane – is an international certification scheme that promotes sustainable production of sugarcane and its derived products – including sugar, ethanol and bio-based materials. The scheme sets requirements for environmental, social and economic conditions throughout the value chain. This includes, among other things, responsible land use, water consumption, working conditions and reduction of greenhouse gas emissions. Bonsucro is used globally and is recognized in the food, energy and materials sectors. It can be used to document sustainability in products containing sugarcane-based ingredients – e.g. bioplastics, bioethanol and packaging.
ISCC PLUS	ISCC PLUS is an international, voluntary certification scheme that documents the sustainability and traceability of bio-based, circular and recycled materials outside the energy sector. It is widely used in industries such as bioplastics, packaging, food, feed, cosmetics, chemicals and textiles. The certification ensures that the origin, production chains and mass balance of raw materials are documented, and that both environmental and social criteria are met. ISCC PLUS is globally recognized, supports both physical segregation and mass balance. It can be combined with ISCC EU for companies operating in both energy and material flows.
Renewable Energy Directive (EU RED III)	EU RED III stands for Renewable Energy Directive III, and it is the third edition of the EU's renewable energy directive. The directive sets a binding target of at least 42.5% renewable energy in the EU’s energy consumption by 2030, with an ambition of 45%. The directive requires increased use of green energy in transport, industry and buildings, and obliges member states to accelerate approvals of renewable energy projects. EU RED III has a list of approved voluntary certification schemes for materials for the production of biofuels, bio-fuels and biomass.

Appendix B Plastic Abbreviations

Abbreviation	Name	Polymer	Additive
ABS	Acrylonitrile butadiene styrene	x	
A-PET	Amorphous polyethylene terephthalate	x	
ASA	Acrylonitrile styrene acrylate	x	
C-PET	Crystalline polyethylene terephthalate	x	
EPS	Expanded polystyrene (foam)	x	
EVOH	Ethylene vinyl alcohol		x
HDPE	High density polyethylene	x	
HIPS	High impact polystyrene	x	
LDPE	Low density polyethylene, aka PELD	x	
PA	Polyamide, aka nylon	x	
PC	Polycarbonates	x	
PE	Polyethylene	x	
PET	Polyethylene terephthalate	x	
PETG	Glycol-modified polyethylene terephthalate	x	
PLA	Polylactic acid	X	
PO	Polyolefins	x	
PP	Polypropylene	x	
PS	Polystyrene	x	
PVC	Polyvinyl chloride	x	

Abbreviation	Name	Polymer	Additive
PVdC	Polyvinylidene chloride		x
R-PET	Recycled polyethylene terephthalate	x	
XPS	Extruded polystyrene (foam)	x	

Appendix C Levels of packaging/Danish national guidelines (Contract appendix 5)

Below table shows the link between the terminologies used in contract appendix 5, the Danish national infection hygiene guidelines and the EU Packaging Directive. Each region maintains its own version of Appendix 5 to the contract, but the overall structure and content are largely the same.

This appendix is therefore only relevant for the Danish regions and their suppliers, but it may be used by other public procurers for inspiration.

The overview below illustrates the alignment between the different terminologies used in Appendix 5 to the contract, the Danish national infection control guidelines, and Regulation 2025/40.

According to the Danish national infection hygiene guidelines, which are described in the Danish Regions' joint contract appendix 5, the three levels of packaging for sterile packaging are referred to as N1, N2 and N3, respectively, cf. below. Packaging for clean (non-sterile products) is referred to as inner and outer packaging.

Sterile products	**Clean (non-sterile) products**	**EU Packaging Directive**
The definition of 'inner packaging' is not used for sterile products since they always contain a primary and secondary packaging. The primary and secondary packaging should always be considered clean and should be handled as such.	***Inner packaging (N1 og/eller N2)*** Inner packaging for non-sterile products may consist of both primary and secondary packaging, or one of the two. Inner packaging aims to protect the product and protect it against contamination in case the transport packaging is opened. It is designed to be stored in rooms without contamination and must be handled by means of clean procedures.	

Sterile products	**Clean (non-sterile) products**	**EU Packaging Directive**
N1: Primary packaging The primary prepacking (individual packaging) is designed to maintain the sterility of the product. In the primary packaging, the products must be packed per product unit, i.e., one piece of the specific product per primary packaging. It must be possible to open the primary packaging in an easy and safe manner with or without gloves in order to ensure the product remains sterile. It must be possible to remove the product from the primary packaging while maintaining its sterility.	***N1: Inner packaging (primary packaging)*** The primary prepacking (individual packaging) for non-sterile products is the inner packaging layer. In the primary packaging, the products must be packed per product unit, i.e., one piece of the specific product per inner packaging. The primary packaging for clean products is the inner packaging layer and must be handled by means of clean procedures.	***Primary packaging*** Sales packaging or primary packaging, i.e., packaging designed to constitute, at the point of sales, a sales unit for the end user or consumer;
N2: Secondary Packaging The secondary packaging (departmental packs) is intended to protect the primary packaging and to safeguard it against contamination when the transport packaging is opened. It is intended for storage in premises free from contamination.	***N2: Inner-packaging (Secondary Packaging)*** The secondary packaging (departmental packs) consists of a grouping of a number of units, regardless of whether it is used as such at final use or for storage purposes, for example in the form of multipacks (departmental packs/combined packs).	***Secondary Packaging*** Multipack or secondary packaging, i.e. packaging designed in such a way that, at the point of sale, it constitutes a grouping of a certain number of sales units, regardless of whether it is sold as such to the final user or consumer, or whether it is used solely for shelf-filling at the point of sale; it may be removed from the product without altering the product's characteristics.

Sterile products	Clean (non-sterile) products	EU Packaging Directive
N3: Tertiary packaging (transport packaging) This layer is considered transport packaging. Transport packaging is the outer layer of packaging in which the product is distributed from the supplier/manufacturer to the customer. The transport packaging protects products against dust, dirt, impact and an insubstantial volume of moisture during transport. Thereby, the transport packaging is unclean and is removed before the product arrives at a clean area where it is stored.	***N3: Outer packaging (transport packaging)*** This layer is considered transport packaging. The outer packaging is the outer layer of packaging in which the product is distributed from the supplier/manufacturer to the customer. The transport packaging protects products against dust, dirt, impact and an insubstantial volume of moisture during transport. Thereby, the transport packaging is unclean and is removed before the product arrives at a clean area where it is stored.	***Transport packaging*** Transport packaging or tertiary packaging, i.e., packaging designed to ease handling and transport of a number of sales units or grouped packaging, to prevent damage caused by physical handling or transport. Transport packaging does not include road, rail, ship and air freight containers.

Tabel 1 Terminologies for levels of packaging in the Danish national guidelines

Please refer to the guidance tool 'Examples of packaging levels', which illustrates packaging levels and can be adapted to the specific tender.

Appendix D Introduction to The Scoring Model

With the purpose of encouraging suppliers (defined as contract holders) to choose packaging with as small climate and environmental consequences as possible, a specific criterion may be applied (criterion 1.3). The criterion is applied by having the supplier fill in the scoring model, which then calculates a score. The score is recommended to be used as a competition criterion in the tender material. The supplier must use the scoring model themselves to calculate a score.

The scoring model may be used for all levels of packaging or exclusively for assessing one or two of the levels of packaging. For instance, for the tertiary and secondary packaging, if the primary packaging is identical for all suppliers due to, e.g., quality requirements. The scoring model is an Excel file: *'Environmental factor scoring calculation'*.

The scoring model is based on a life cycle assessment, which consists of a screening of various categories of materials. Together with the weight of the materials, the scoring model lets you compare the total climate and environmental consequences of the packaging production, starting with the extraction and production of the material (excluding, though, production of the packaging).

The scoring model gives an overall environmental score that can be used directly in tender processes, allowing for the assessment of tenders without including an environmental expert in the tender process. The factors are indicative and will not necessarily match the results of a life cycle assessment of a specific packaging product.

Selection of products for the scoring model
If more than five products are included in the tender material, it is recommended to only fill in the scoring model for a number of selected products. See appendix E.1.3.

User guide
Specify the weight, materials as well as other information about all packaging elements, including accompanying user guide and/or leaflet. Based on the information, the scoring model calculates a score for all the packaging elements for the specific product. The score is calculated based on integrated index values for the different types of materials that you can choose between in the model. A complete guide on how to fill in the scoring model is available in the 'Introduction' tab in the scoring model. You can see an example of how to fill in the scoring model in the 'Example description' tab - 'Example - Scoring model'.

If the tenderer takes back the packaging in order to reuse it or if the packaging is being part of an established standardized take-back scheme as, e.g., EUR-pallets, the packaging is given a weight of 0 g in the model.

The higher the score, the more positive assessment of the packaging.

Materials included in the scoring model
The scoring model includes metal, plastics and cellulose-based material in the different categories in a virgin and recycled version, and for plastic also a bio-based version (based on first-generation and, in part, second-generation - for more information, see below the table).

The tender material should state what the supplier should do if they have a material that is not covered by the scoring model.

Material	Specification	Explanation
Metals Including metal foil. The most common material is assessed to be aluminium; hence the factors are mainly based hereon.	Aluminium	
Plastics Including plastic laminates and plastic non-reusable plastic pallets. The most common material is assessed to be LDPE, hence the factors are mainly based hereon.	Virgin	Virgin plastic produced from fossil sources that is currently recycled within the Danish healthcare sector. A distinction is made between: • HDPE • MDPE • LDPE • PP • PET • Other plastics
	Virgin	Virgin plastic produced from fossil sources that is currently not recycled within the Danish healthcare sector. A distinction is made between: • PC • PVC • EPS/PS • Nylon • Other plastics
	Recycled	Mechanically recycled plastic is defined as products/packaging containing 100% recycled plastic. A distinction is made between: • Recycled HDPE • Recycled PET
	Bio-based	Biobased plastic is defined as polymers derived from biomass that are not biodegradable, including compostable polymers. Biobased plastic must meet requirements for a certified supply chain.
Cellulose-based material For instance, cardboard and paper	Virgin or recycled	Cardboard and paper are not further differentiated, as their climate impacts and recycling characteristics are largely similar. Accordingly, a single combined factor is currently applied for virgin and recycled cardboard and paper.

Table 2 Definitions and information about the types of materials available in the scoring model

Bio-based plastic

Since the scoring model was prepared in the autumn of 2021, the market for bioplastics has developed rapidly. In the scoring model, bio-based plastic is, as described, primarily based on first-generation bioplastic. Consequently, if suppliers can deliver second-generation or third-generation bioplastic, it is not fair to use the bioplastic score in the current form of the scoring model. A new scoring model is being prepared.

Please note that biodegradable polymers, including polymers that are compostable, are not permitted, cf. criterion 2.2. If you do not want suppliers to use first-generation bioplastic, this can be stated in this criterion.

Overall score

The final score is stated per product. The underlying calculations in the model multiply the number of each packaging element by the weight of the relevant packaging element and divide the result by the number of products in the delivery.

It is the final score (indicated in cell M10) that is used in the tender. The lower the score, the better the points awarded in the evaluation of the tender. All other tender scores are interpolated in relation to the best tender.

Appendix E Market Dialogue

The market dialogue can be used to identify relevant sustainability criteria at a suitable level, and decide whether each criterion should be a minimum or a competition criterion. Hereby, the level of ambition for the tender process is determined based on what suppliers are able to deliver. Moreover, a market dialogue is a useful way of understanding the levels of packaging in the specific tender process and making sure that suppliers understand the definitions of the levels of packaging.

It is important to give suppliers enough time to gather information/documentation for the market dialogue. A consultation period of at least two months is suggested (longer in the summer as the summer break is taken at different times across Europe).

The market dialogue is recommended to be a combination of written communication as well as oral dialogue with suppliers to make sure that you obtain the requested product-related information.

In the following, a number of topics exemplify what may be useful to discuss with suppliers in the market dialogue.

Selection of sustainability criteria and setting of level of ambition
It is recommended to use the market dialogue to study what criteria suppliers may meet and at what level[17]. This can be used to select relevant criteria at a suitable level.

One way of gathering this information is shown in the template *"Markedsdialog – Excel skabelon - leverandørtilbagemelding til udvælgelse af kriterier"*, which is a fictive example of how to select criteria based on feedback from suppliers in the market dialogue (either by having the bid manager fill it in during the actual market dialogue, or by written feedback from suppliers).

The library of criteria is forwarded/announced to suppliers in the Excel template, and suppliers/bid managers use the colour code red, yellow and green to indicate how hard/easy it is for them to meet the requirements applicable to the different levels. This is done for all criteria for all levels (basic, advanced and spearhead).

This allows tender consultants to set the right level for the criteria that are selected for the tender process, and determine whether the criteria should be minimum or competition criteria. The library of criteria is a gross list and the level of ambition is indicative. The level of ambition for the specific call for tenders is determined based on the market dialogue, by the tender process manager.

Process of collecting knowledge for selection of criteria
The following is an example of how the process of selecting sustainability criteria may be. The example is based on a specific call for tenders where the market dialogue contributed positively to the preparation of tender documents. Prior to a physical meeting, suppliers had received *"Nordic criteria for more sustainable packaging"* containing the library of criteria.

Suppliers were asked to answer the following questions:

[17] The market dialogue is available at https://www.regioner.dk/regional-udvikling/groenne-hospitaler/indkoeb/emballagekriterierne/

Which criteria they were/were not able to meet – and at which level (basic, advanced and spearhead). The suppliers were asked to fill in *"Markedsdialog – Excel skabelon – leverandørtilbagemelding til udvælgelse af kriterier"*.

Whether any criteria were unclear, lacking further elaboration.

Whether any of the criteria were irrelevant.

Despite a well-prepared market dialogue, it is our experience that not all suppliers are able to clearly state which criteria they would be able to meet at which level. Experience from specific market dialogues has shown that it is important to inquire about suppliers' answers and to see the packaging (physically or images of it).

Selection of products for evaluation
In the case of a tender process involving several products, a number of products should be selected to which the sustainability criteria are applied. This to ease the work for suppliers and tender consultants. It is suggested to use the market dialogue to look into which products have the largest volume of packaging. For instance, the products that should be prioritised in the contract may be chosen based on which products:

1. account for the largest total volume,

2. have the most layers of packaging, or

3. where a modified packaging will have the largest environmental impact (e.g., products with unnecessary large packaging and/or metal packaging).

The selection parameters should be determined in the bill of quantities.

Appendix F Packaging minimisation (standard DS/EN 13428)

The following section describes how the supplier documents that the weight and volume of the packaging have been reduced.

One of the purposes of the criteria for more sustainable packaging is to reduce material consumption. The suppliers can use the principles of the DS/EN 13428 standard to document that the company has reduced the weight and volume of the packaging based on ten performance criteria. These are described in Annex A of the standard.

It is important that the performance (functionality and safety) of the packaging as well as the customer's acceptance remain unchanged or sufficient. The supplier must assess all ten performance criteria when working systematically on minimising packaging weight and/or volume. The supplier must do this to ensure that all potentials for minimisation are considered and to identify critical aspects of packaging performance. The latter is important to ensure that the packaging maintains sufficient functionality and safety.

The ten performance criteria are:

- Product protection
- Packaging manufacturing process
- Packing/filling process
- Logistics
- Product presentation and marketing
- User/consumer acceptance
- Information
- Safety
- Legislation
- Other issues.

Appendix G Introduction to the Packaging and Packaging Waste Regulation 2025/40

This annex provides a brief introduction to the Packaging and Packaging Waste Regulation 2025/40.

Purpose of directive

The overall goal is that all packaging in the EU is recyclable or reusable by 2030. The key means to achieve this goal are:

- Reduce the amount of packaging placed on the market in terms of volume and weight, including limiting void space in transport packaging.
- Strengthen high-quality recycling systems, including facilitating sorting for recycling by using clear and harmonised symbols, possibly through digital data carriers.
- Limit and phase out the presence of problematic and harmful substances in packaging throughout their life cycle to protect human health and the environment.
- Encourage the use of recyclable packaging.
- Establish schemes for Extended Producer Responsibility Based on the principle that the 'polluter pays', all costs for the treatment of packaging waste must be borne by the producer.
- Public procurement must at least meet mandatory requirements, cf. the Regulation, by setting transparent, objective and non-discriminatory conditions. Contracting authorities may adopt provisions that go beyond the minimum requirements adopted in the Regulation.

The Directive covers all packaging placed on the market in the European Union (EU) and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used.

Packaging for the healthcare sector will be covered by the regulation, however, contact packaging where there may be a risk of diffusion, primary packaging for medical devices and medicines, and foods for medical foods (such as infant formula and other nutritional products) will be exempt from the requirement for recyclable packaging.

Recycling targets

No later than on 31 December 2030, at least 70 percentage by weight of all packaging must be recycled.

By December 31st 2030, the following minimum recycling targets by weight must be met for the following specific materials included in generated packaging waste:

- 55% of plastic
- 30% of wood
- 80% of ferrous metals
- 60% of aluminium

- 75% of glass
- 85% of paper and cardboard[18]

In general, the long-term strategy behind the common Nordic packaging criteria for the healthcare sector will support the regulation.

[18] Regulation 2025/40, Article 52, paragraph 1, points (b) and (c)

Appendix H EU Declaration of Conformity

This is an example of a declaration of conformity. It can be used as documentation for the criteria where this is stated:

Documentation for the declaration of conformity must contain the following information according to Annexes VII and VIII of Regulation 2025/40.

1. No. … (unique identification of the packaging):

2. Name and address of the manufacturer and, where applicable, of the manufacturer's authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of the packaging so that it can be traced): description of the packaging:

5. The subject matter of the declaration referred to in point 4 is in conformity with the relevant Union harmonisation legislation: … (reference to other Union acts applied).

6. References to the relevant harmonised standards or common specifications applied or references to other technical specifications with which conformity is declared:

7. Where applicable, the notified body … (name, address and number) … which carried out … (description of the activity) … and issued the certificate(s): … (details, including the date of the certificate(s) and, where applicable, information on the period of validity and conditions of validity).

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name and position) (signature):