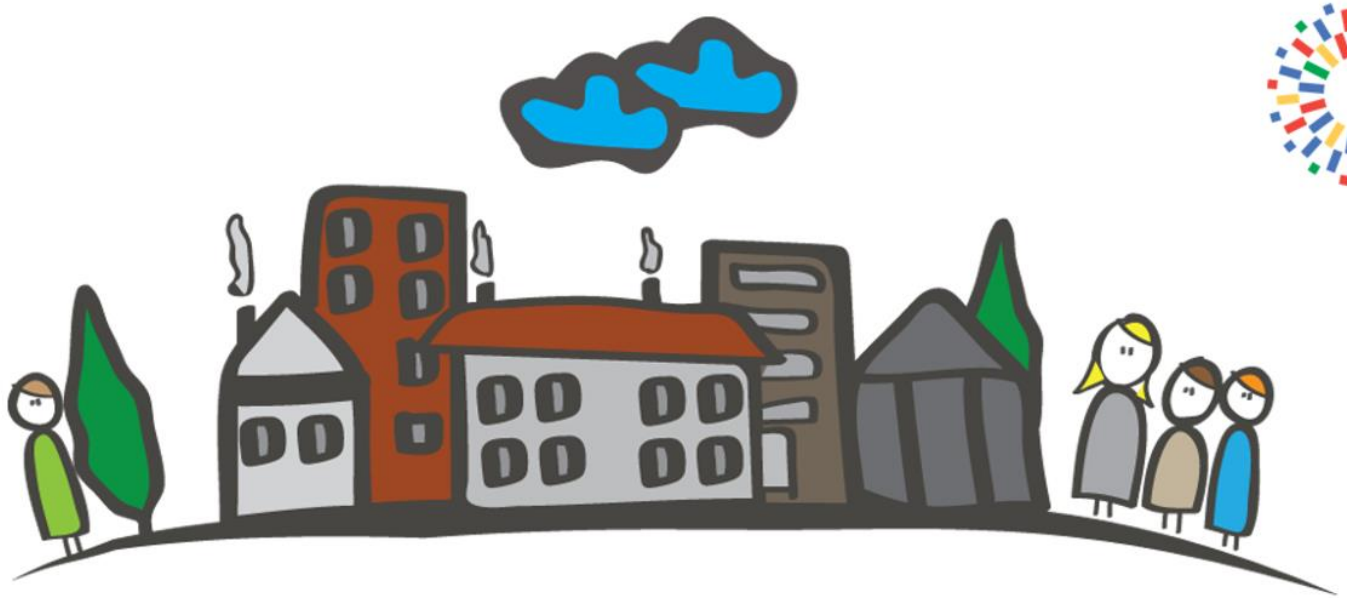
Guide to Medical Equipment Classification



NORWEGIAN
SMART CARE
LAB

The service package is delivered by subcontractor Egde in cooperation with NSCL

Medical equipment classification

Through a structured process, Egde will guide the customer to the correct classification of the product in connection with an approval process for medical equipment.

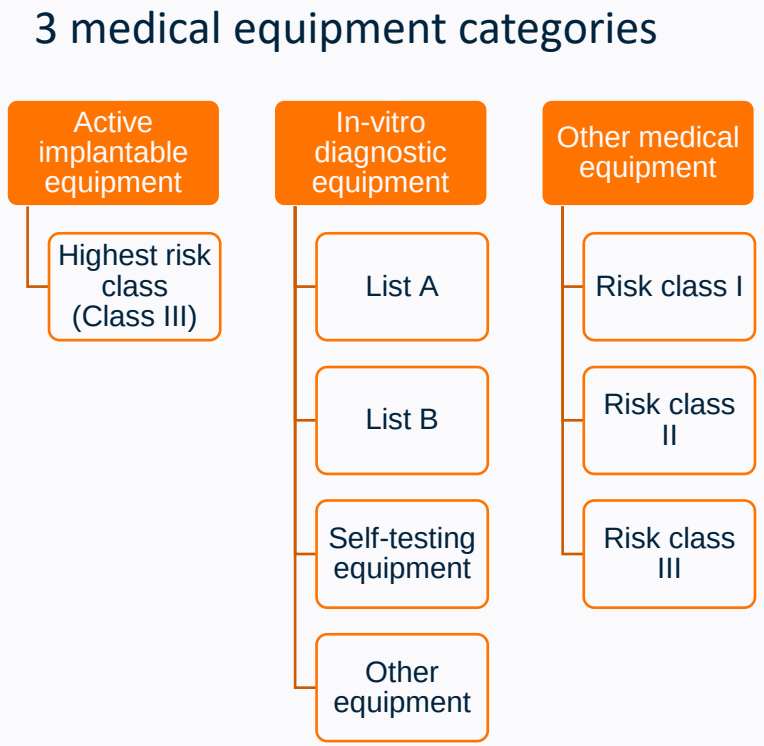
The service package provides access to professionals with experience in existing regulations for medical classification and will ensure the customer good guidance in accordance with current requirements for product and risk class.

Classification

Classification of medical equipment takes place in two steps. The first step is to determine if the product qualifies as a medical device. If the answer to this is "YES", the next step is to determine the equipment's risk class.

The decision on whether the product/solution is a medical device shall be based on the company's intended use of the product. The purpose is then assessed against the legal definition given in Article 2 of the MDR or IVDR.

The purpose of the product must also be compatible with the mechanisms of action and claims that accompany the equipment during marketing.



This service package will guide the customer through a process to find the correct classification of their solution / product as medical equipment. Proper classification is important to identify the correct requirements for approval of the product as a medical device.

Step 1 – Workshop – Product classification

In the workshop, the customer presents their solution with relevant background information and data for Egde's experts. Egde will present important aspects in the classification process for the customer so that a good foundation is laid for a common understanding of the product category.

The workshop will also clarify information needs, issues and further progress.

Objectives: Facilitate good discussions so that through a common understanding the cvompany arrives at an overall classification of the product category.

Expected duration: 2-3h

After the meeting:

- The customer is expected to send relevant written information to Egde as agreed in the workshop
- Egde maps relevant information related to issues from the first workshop and prepares the next workshop where the focus will be risk classification

Step 2 – Workshop – Risk classification

Through introductory meetings, the product's functions and the appropriate product classification will have been mapped. In this workshop the solution will be assessed based on the medical classification established in the first workshop and submitted material from the customer. Egde's experts will facilitate an in-depth study of risk classification based on this assessment.

During the workshop, Egde will guide and in collaboration with the customer define the equipment's risk class.

Objectives:

- Clarify, quality assure and conclude the customer's information about the product
- Agree on recommended risk class

Expected duration: 2-3h

After the meeting: Egde and the customer make the necessary clarifications that form the basis for Egde's recommendation

Company input: Provide appropriate professional resources for the workshop

Summary

1 Workshop – Product classification

2 Workshop – Risk classification

Report and presentation

Get in touch if you want more information about what the package contains and what the lab can offer your company.

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