



NORWAY MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Norway

START HERE: WHAT IS THE PRODUCT IN NORWAY?

1 Confirm the Norwegian regulatory identity

Determine whether the product is a medical device, accessory, software, implantable, or custom-made device under the MDR framework applied in Norway.

Class I, IIa, IIb, III — special features drive extra controls.



General device



Software / digital



Implant / active / sterile

2 Choose the regulatory route

CLASS I



Lowest risk

Self-declaration
in most cases.

CLASS IIa



Moderate risk

Notified Body
involvement
required.

CLASS IIb



High risk

Deeper technical
and clinical
review.

CLASS III



Highest risk

Strongest evidence
and surveillance
burden.

3 Build the Norway market-access infrastructure



EUDAMED + SRN

Register actors and
devices in EUDAMED
as required.



AR / importer

Set up EU/EEA
Authorized Representative
when needed and assign
importer duties.



Language plan

Norwegian language
obligations must be built
into launch planning.



Operator readiness

UDI, PMS, vigilance,
and importer/distributor
controls must be
established.

4 Build the evidence stack



Administrative
Route strategy,
declarations,
operator data.



Quality / QMS
ISO 13485 style
controls, PRRC,
suppliers.



Technical / V&V
Bench, software,
EMC, biocompatibility,
sterilization as
applicable.



Clinical evaluation /
PMCF
Proportional to
class and
novelty.



Labeling / IFU
Safe-use
information and
launch
documentation.



RA TRAP TO AVOID

Do not treat Norway as a simple copy-paste
of EU launch without Norwegian language
readiness.



STRATEGIC INSIGHT

For many devices, the route is CE-based —
but Norwegian labeling, documentation access,
and EUDAMED readiness still decide
launch quality.



NORWAY MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to launch — where the decision points and real-world friction sit

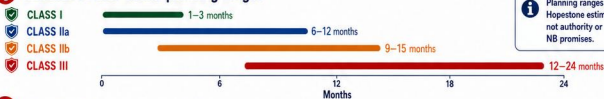
A Program flow



B What gets heavier as the class rises?

Signal	CLASS I	CLASS IIa	CLASS IIb	CLASS III
Premarket pathway	Self-declaration	NB assessment	NB assessment	NB assessment + design dossier
Evidence intensity	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical evaluation / PMCF	Not usually required ● ● ● ● ●	Required (often) ● ● ● ● ●	Extensive ● ● ● ● ●	Extensive + PMCF ● ● ● ● ●
QMS readiness	Basic ● ● ● ● ●	Mature ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges



i Planning ranges are Hoptstone estimates, not authority or NB promises.

D Labeling & language essentials



Norwegian language
Information for safe and correct use must be in Norwegian for both general and professional use.



Technical documentation
At authority request, documentation may be provided in Norwegian or English.



Declaration of Conformity
The DoC may be in English or Norwegian.



Implant cards / eIFU
Implant cards and patient information for implants must be in Norwegian; eIFU content must also meet Norwegian language rules.

E Country-specific decision points



EUDAMED
Actor registration and device registration in EUDAMED are mandatory.



Timing
For devices placed before 28 May 2026, EUDAMED registration must be completed by 28 Nov 2026.



Custom-made nuance
Custom-made implantable Class III devices carry extra MDR control.



Primary resources
dmp.no
europa.eu



IMPORTANT: Confirm product-specific requirements before execution.