



NETHERLANDS MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering the Dutch market

START HERE: WHAT IS THE PRODUCT IN THE NETHERLANDS?

1 Confirm the Dutch regulatory identity

Decide whether the product is an MDR medical device, accessory, software, or custom-made device; identify intended use, users, and claims.

Class and special features such as sterile, measuring, reusable surgical instrument, or implantable status affect the route.

Non-EU manufacturers need an EU Authorized Representative.



General device



Software / digital



Sterile / implant / custom-made

2 Choose the regulatory route

CLASS I



Lowest risk

Self-declaration in most cases
Sterile, measuring, or reusable surgical instrument variants need Notified Body involvement for the relevant aspects.

CLASS IIa



Moderate risk

NB review required
Technical documentation and QMS oversight increase.

CLASS IIb



High risk

Deeper NB review
Clinical and post-market expectations are stronger.

CLASS III



Highest risk

Most demanding MDR route
Implantable and other highest-risk devices face the heaviest evidence burden.

3 Build the Dutch market-access infrastructure



EUDAMED + SRN

Register economic operators and device data in EUDAMED as required.



EU AR / importer

Set up EU Authorized Representative, importer, and distribution responsibilities.



NOTIS for custom-made

In the Netherlands, custom-made devices are registered in NOTIS.



Clinical investigation

Use CCMO routes when a clinical investigation is required.

4 Build the evidence stack



Administrative
Classification rationale, declarations, operator data, and route strategy.



Quality / QMS
ISO 13485 style QMS, PRR, suppliers, risk management, CAPA.



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



Clinical evaluation
Clinical evaluation and PMCF scaled to class, novelty, and claims.



Labeling / UDI
MDR Annex I labeling, UDI planning, and launch labeling readiness.



RA TRAP TO AVOID

Do not assume NOTIS replaces EUDAMED for ordinary MDR devices.



STRATEGIC INSIGHT

The Netherlands is mainly an EU MDR route plus Dutch execution on EUDAMED, custom-made registration, and economic-operator setup.



NETHERLANDS 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-declare ● ● ● ● ●	NB involvement (limited) ● ● ● ● ●	NB assessment ● ● ● ● ●	NB scrutiny (highest) ● ● ● ● ●
Evidence intensity	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical evaluation / PMCF	Basic ● ● ● ● ●	Standard ● ● ● ● ●	Advanced ● ● ● ● ●	Extensive ● ● ● ● ●
Quality-system readiness	Basic ● ● ● ● ●	Detailed ● ● ● ● ●	Comprehensive ● ● ● ● ●	Robust ● ● ● ● ●
Post-market control	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●

C Indicative route-based planning ranges



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

D Labeling & language essentials

MDR labeling
 Meet Annex I label and IFU requirements; confirm Dutch user-facing language needs for the intended users.

UDI readiness
 Place UDI on label/packaging as required and register it in EUDAMED.

Custom-made nuance
 Custom-made devices do not need UDI; custom-made implantable Class III devices have added MDR control.

Post-market
 Vigilance, trend reporting, FSQA, PMS/PMCF, and distributor/importer control must be launch-ready.

E Country-specific decision points

EUDAMED timing
 Mandatory registration applies from 28 May 2026; legacy timing runs to 28 Nov 2026.

NOTIS
 In the Netherlands, custom-made devices are registered in NOTIS; a complete notification can take up to 90 days.

Clinical route
 Use CCMO pathways when clinical investigations are needed.

Primary resources
english.farmatec.nl
business.gov.nl
ccmo.nl
europa.eu