

Chapter 11 Template: Notified Body Selection Framework

Subtract to Ship: MDR Certification*, Chapter 11: Choosing a Notified Body

Instructions

Treat NB selection as a strategic decision, not an administrative checkbox. The difference between the right NB and the wrong NB is 6 months vs. 18 months. Start this process immediately after your intended purpose is defined and classification is determined. This template walks you through the five-variable framework.

Part 1: Your Requirements

Field	Your Answer
Device classification	Class _
MDR codes (from NANDO database)	
Conformity assessment procedure (Article 52)	
Primary language of documentation	
Company location	
Target submission date	
Cash runway remaining	_ months

Part 2: NANDO Database Filtering

Go to: ec.europa.eu/growth/tools-databases/nando

1. Filter by Regulation (EU) 2017/745
2. Filter by your MDR codes
3. List all designated NBs that cover your codes:

NB Name	NB Number	Country	Covers Your MDR Codes?
			Yes
			Yes
			Yes
			Yes
			Yes
			Yes
			Yes

Part 3: Five-Variable Scoring

Score your top 3-5 candidates on each variable (1-5 scale, 5 = best):

Variable	NB 1:	NB 2:	NB 3:
V1: MDR Code Match (must be YES)	Yes No	Yes No	Yes No
V2: Technology Fit (experience with your device type)	/5	/5	/5
V3: Language Match (review team works in your doc language)	/5	/5	/5
V4: Geography (proximity for on-site audits)	/5	/5	/5
V5: Speed vs. Brand (capacity + timeline vs. name recognition)	/5	/5	/5
Total	/20	/20	/20

Notes per NB

NB 1: - Estimated review timeline:

- Estimated fees: EUR

- Technology experience notes:

NB 2: - Estimated review timeline:

- Estimated fees: EUR

- Technology experience notes:

NB 3: - Estimated review timeline:

- Estimated fees: EUR

- Technology experience notes:

Part 4: First Contact Checklist

For each candidate NB, make a phone call (not email). Cover these points:

Question	NB 1	NB 2	NB 3
Current capacity for new applications?			
Estimated timeline from application to first feedback?			
Experience with your specific technology type?			
Do they have auditors who work in your language?			
Are they willing to work with startups?			
Can they handle both QMS and product assessment (Annex IX)?			
Responsiveness and communication quality?			

Part 5: Selection and Engagement Timeline

Step	Target Date	Status
NANDO database filtering completed		☐
Short list of 3-5 candidates built		☐
Informal first contact with top 3		☐
Preferred NB selected		☐
Letter of Intent sent		☐
Formal application submitted		☐

Recommended Timeline

Period	Action
Month 1-2 (after intended purpose defined)	NANDO filtering, short list
Month 2-3	First contact with top candidates
Month 3-4	Select preferred NB, send Letter of Intent
Month 4+	Continue documentation build, maintain NB contact

Part 6: Readiness Assessment

Before submitting to your NB, answer honestly:

- ☐ Intended purpose is defined in writing and finalised
- ☐ Classification is determined and documented
- ☐ QMS is operational (not just documented, people follow it)
- ☐ Technical documentation follows Annex II structure
- ☐ Clinical evidence strategy is defined
- ☐ Risk management file exists
- ☐ A gap analysis has been conducted (by someone with NB audit experience)
- ☐ I have a backup NB identified in case the primary declines or disappears

If fewer than 6 checked: Consider investing in a pre-submission readiness assessment before submitting. A few thousand euros now beats a rejection and 6-month restart later.

Part 7: NB Relationship Principles

- ☐ I understand the NB is a partner, not an adversary
 - ☐ I will submit documentation that is "good enough" (complete and honest), not wait for "perfect"
 - ☐ I will flag known gaps honestly rather than trying to hide them
 - ☐ I will maintain ongoing dialogue, not just annual audit contact
 - ☐ I will use the same NB for QMS and product assessment (Annex IX)
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Selected NB:

NB Number:

First contact date:

LOI sent date:

Completed by:
