Chapter 6 Worksheet: Device Classification & Conformity Assessment Procedure

Subtract to Ship: MDR Certification, Chapter 6: Classification*

Instructions

Block two hours. Open MDR Annex VIII (current consolidated text). Walk through every classification rule systematically with your intended purpose from Chapter 5 in hand. Do not skip rules because they "seem irrelevant." The implementing rule (Annex VIII Section 3.5) says the strictest applicable rule wins.

Part 1: Input, Your Intended Purpose

Copy your finalised intended purpose from Chapter 5 here:

If this is not finalised: STOP. Go back to Chapter 5. Classification without a clear intended purpose is classification on sand.

Part 2: Systematic Rule Walk-Through

For each rule group, assess whether it applies to your device. Document your reasoning.

Rules 1-4: Non-Invasive Devices

Rule	Description	Applies?	Resulting Class	Reasoning
Rule 1	All non-invasive devices (default Class I)	Yes No		
Rule 2	Channelling/storing blood, body fluids, tissues	Yes No		
Rule 3	Modifying biological/chemical composition for infusion	Yes No		
Rule 4	Contact with injured skin	Yes No		

Rules 5-8: Invasive Devices

Duration of contact: Transient (<60 min) Short-term (60 min - 30 days) Long-term (>30 days)

Rule	Description	Applies?	Resulting Class	Reasoning
Rule 5	Non-surgically invasive (body orifice)	Yes No		
Rule 6	Surgically invasive, transient use	Yes No		
Rule 7	Surgically invasive, short-term	Yes No		
Rule 8	Implantable / long-term surgically invasive	Yes No		

Rules 9-13: Active Devices

Rule	Description	Applies?	Resulting Class	Reasoning
Rule 9	Active therapeutic devices	Yes No		
Rule 10	Active diagnostic devices	Yes No		
Rule 11	**Software** (pay special attention)	Yes No		
Rule 12	Administering/removing medicinal products	Yes No		
Rule 13	All other active devices (Class I)	Yes No		

Rule 11 Deep Dive (if applicable)

Software Function	Classification
Software for diagnostic/therapeutic decisions	Class IIa (baseline)
Sub-case: decisions that could cause death or irreversible deterioration	Class III
Sub-case: decisions that could cause serious deterioration or surgical intervention	Class IIb
Software for monitoring physiological processes	Class IIa
Sub-case: monitoring vital parameters where variations = immediate danger	Class IIb
All other software	Class I

Your software function:

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Resulting class from Rule 11:

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Rules 14-22: Special Rules

Rule	Description	Applies?	Resulting Class	Reasoning
Rule 14	Incorporates ancillary medicinal substance	Yes No		
Rule 15	Contraception / STD prevention	Yes No		
Rule 16	Disinfecting / sterilising devices	Yes No		
Rule 17	X-ray diagnostic imaging	Yes No		
Rule 18	Animal / human tissues	Yes No		
Rule 19	Nanomaterials	Yes No		
Rule 20	Inhaled medicinal product administration	Yes No		
Rule 21	Substances introduced into the body	Yes No		
Rule 22	Active therapeutic + integrated diagnostic	Yes No		

Part 3: Implementing Rule (Annex VIII Section 3.5)

List every rule that applies and the class it gives you:

Applicable Rule	Resulting Class

The highest class from any applicable rule is your classification.

Your device classification: Class

Qualifiers

- [ ] Measurement function
- [ ] Supplied sterile
- [ ] Reusable surgical instrument

Part 4: Conformity Assessment Procedure (Article 52)

Your Class	Conformity Assessment	NB Required?
Class I (no qualifiers)	Self-declaration (Annex II + III)	No
Class I (sterile/measurement/reusable)	Self-declaration + NB for specific aspects	Partial
Class IIa	Annex IX (QMS + technical documentation) or alternatives	Yes
Class IIb	Annex IX with more comprehensive assessment	Yes
Class III	Full Annex IX or Annex X + XI	Yes

Your conformity assessment procedure:

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Part 5: Grey Zones

Are there any rules where your classification could be argued either way?

Grey Zone	Rules in Conflict	Your Position	Evidence Needed

Grey zones require expert input. A 2-hour conversation is cheaper than 18 months built on the wrong classification.

Part 6: Cost and Timeline Implications

Class	Approximate Cost Range	Approximate Timeline
Class I (no NB)	EUR 21,000-90,000	6-12 months
Class IIa (with NB)	EUR 191,000-350,000	12-24 months
Class IIb (with NB)	EUR 360,000-925,000	18-36 months
Class III (with NB + clinical)	EUR 500,000-2,000,000+	24-48 months

Your estimated cost range: EUR

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Your estimated timeline:

_ months

Does your funding cover this (after applying the Double-It Rule)? Yes No

Decision Gate

- [ ] Intended purpose is finalised
- [ ] All 22 rules walked through systematically
- [ ] Implementing rule applied (highest class from any applicable rule)
- [ ] Conformity assessment procedure identified
- [ ] Grey zones identified and flagged for expert review
- [ ] Cost and timeline implications understood

Classification confirmed. Next step: Chapter 7 (Team & Competences)

Date completed:

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Completed by:

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Classification: Class

Conformity route:

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