PROCEDURE FOR CLASS I MEDICAL DEVICE REGULATORY REVIEW AND APPROVAL (SELF-DECLARATION)

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1. Purpose

To define the procedure for the review of medical devices classified as **Class I** under **EU MDR (EU) 2017/745** where conformity assessment does not require the involvement of a Notified Body, except for specific Class Is, Im, and Ir devices.

This procedure ensures that regulatory documentation is reviewed in accordance with applicable European Union legislation before issuing a conformity assessment report.

2. Scope

This procedure applies only to:

- Class I Medical Devices
- Self-declared medical devices
- Non-sterile devices
- Non-measuring devices
- Non-reusable surgical instruments

This procedure does **not** apply to:

- Class Is
- Class Im
- Class Ir
- Class IIa
- Class IIb
- Class III
- Active Implantable Medical Devices

3. Reference Documents

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- Regulation (EU) 2017/745 (EU MDR)
- Annex VIII – Classification Rules
- Annex II – Technical Documentation
- Annex III – Post Market Surveillance
- Annex IV – EU Declaration of Conformity
- Annex I – General Safety and Performance Requirements (GSPR)
- ISO 14971
- ISO 13485 (where applicable)
- MDCG Guidance Documents

4. Policy

The organization performs an **independent technical review** only for devices legally eligible for self-declaration under MDR.

The organization **does not act as a Notified Body**.

The organization **does not issue CE Certificates requiring Notified Body intervention.**

5. Responsibility

Technical Reviewer

- Review classification
- Verify intended purpose
- Verify applicable legislation
- Review technical file
- Prepare review report

Technical Manager

- Verify reviewer conclusions
- Approve final report

Certification Manager

- Issue Compliance Report

- Issue voluntary conformity letter (where applicable)

6. Procedure

Step 1

Receive application.

Applicant submits

- Device description
- Intended purpose
- Classification
- Technical File
- Risk Management File
- Clinical Evaluation
- Label
- IFU
- EU Declaration of Conformity

Step 2

Determine Device Classification.

Classification is verified according to MDR Annex VIII.

Decision:

Is device Class I?

YES → Continue

NO → Reject application.

Step 3

Verify Notified Body Requirement.

Reviewer checks whether device is

- Sterile

- Measuring
- Reusable Surgical Instrument

If YES

Application cannot proceed.

Customer shall be informed that Notified Body involvement is mandatory.

Step 4

Technical Documentation Review

Review

- Intended Purpose
- Essential Safety Requirements
- Risk Analysis
- Clinical Evaluation
- PMS Plan
- Label
- IFU
- UDI (if applicable)

Step 5

Applicable Standards Review

Verify applicable standards.

Examples

ISO 14971

IEC 60601

ISO 10993

ISO 15223

IEC 62366

IEC 62304

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(only where applicable)

Step 6

Compliance Review

Reviewer evaluates

- MDR Annex I
- Annex II
- Annex III
- Annex IV

Any nonconformity shall be documented.

Step 7

Final Decision

If documentation complies,

Issue

- Technical Review Report
- Compliance Assessment Report
- Voluntary Letter of Conformity (if within organization's scope)

Do **not** issue:

- EU MDR CE Certificate
- Notified Body Certificate
- EC Design Examination Certificate

8. Justification

According to **Article 52 of Regulation (EU) 2017/745**, manufacturers of **Class I medical devices** (excluding sterile, measuring, and reusable surgical instruments) perform the conformity assessment under their own responsibility without the involvement of a Notified Body.

Therefore, the organization may review the technical documentation and provide an independent compliance assessment or voluntary conformity report, but **cannot issue an EU MDR CE certificate that is reserved for Notified Bodies designated under Article 35 of the MDR**.

9. Limitations

The organization:

- Is not designated as an EU Notified Body.
- Does not allocate a Notified Body identification number.
- Does not issue CE certificates under Annex IX, Annex X, or Annex XI of MDR.
- Does not authorize placement of the CE mark on behalf of the manufacturer.
- Provides only independent technical review and voluntary conformity assessment within the scope of Class I self-declared devices.

10. Records

The following records shall be maintained:

- Application Form
- Classification Review
- Technical File Review Checklist
- Risk Review Report
- Compliance Assessment Report
- Approval Record
- Final Decision Record

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Common EU MDR Class I Product Examples

The following products can commonly fall under **Class I, non-sterile and non-measuring**, depending on their intended purpose and design:

Product category	Indicative products
Examination and diagnostic accessories	Examination lamps, manual examination tables, non-powered patient positioning aids
Hospital furniture	Manual hospital beds, bedside tables, examination couches, medical stools
Mobility aids	Manual wheelchairs, walking sticks, crutches, walking frames, rollators
Patient-support products	Arm slings, simple limb supports, cervical collars for minor support, positioning cushions
Non-invasive measuring accessories without a measuring function	Stethoscope holders, equipment stands, device mounting brackets
General examination instruments	Tongue depressors, neurological reflex hammers, tuning forks intended for medical examination
Non-sterile wound-care products	Simple adhesive bandages, non-sterile gauze, non-sterile cotton rolls, non-sterile wound pads
Personal protection for medical use	Non-sterile examination gloves, non-sterile medical masks, non-sterile protective gowns—subject to intended purpose
Dental accessories	Manual dental mirrors, impression trays supplied non-sterile, dental mixing instruments
Rehabilitation products	Simple exercise bands intended for rehabilitation, balance boards, manual physiotherapy supports
Ophthalmic accessories	Trial spectacle frames, occluders, eye-test charts
ENT examination accessories	Non-sterile ear funnels/specula, simple nasal examination accessories

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Product category	Indicative products
Medical containers	Specimen containers supplied non-sterile and without a measuring function
General surgical accessories	Instrument trays and bowls supplied non-sterile, subject to intended use
Patient transfer products	Manual stretchers, transfer boards, evacuation chairs
Medical furniture accessories	IV stands without active control, bed rails, mattress supports
Simple first-aid devices	Ice bags, hot-water bags, simple first-aid splints
External anatomical supports	Abdominal belts, maternity-support belts, simple knee/elbow supports
Medical apparel	Patient examination gowns and procedure apparel where the claimed medical purpose supports medical-device qualification
Medical software with very limited function	Software that only stores, archives, transfers or displays information without diagnostic or therapeutic decision-making may be Class I or may not qualify as a medical device, depending on functionality

Products Commonly Considered Class I in Multiple Markets

These product types often fall within the lowest-risk medical-device class in the EU, UK, Australia, United States or Canada, but country-specific verification is still required:

1. Manual wheelchairs
2. Walking sticks and crutches
3. Walking frames
4. Manual hospital beds
5. Examination couches
6. Manual stretchers
7. Patient transfer boards
8. Tongue depressors

9. Reflex hammers
10. Tuning forks for examination
11. Non-sterile gauze
12. Non-sterile bandages
13. Non-sterile examination gloves
14. Non-sterile medical gowns
15. Simple arm slings
16. Basic orthopedic support belts
17. Simple knee and elbow supports
18. Ice packs and hot/cold packs without medicinal substances
19. Manual dental mirrors supplied non-sterile
20. Non-sterile dental impression trays
21. Urine or specimen containers without measurement claims
22. Medical instrument trays supplied non-sterile
23. Bedside commodes
24. Patient lifting accessories without active powered control
25. Simple rehabilitation exercise devices
26. Medical examination lights without diagnostic analysis
27. Wheelchair cushions intended only for positioning
28. IV poles without infusion-control functions
29. Eye occluders
30. Trial spectacle frames
31. Snellen or visual-acuity charts
32. Non-powered suction accessories without direct patient-contact risk
33. Non-sterile disposable bed sheets for a defined medical purpose
34. Simple first-aid splints
35. Manual patient turning devices
36. Medical equipment stands and trolleys

37. Non-invasive patient positioning wedges
38. Manual breast pumps, depending on jurisdiction and claims
39. Simple medicine spoons without an accurate measuring claim
40. Basic medical storage and transportation containers where they qualify as device accessories

Country Comparison

Market	Lowest-risk category	Typical route
European Union	Class I	Manufacturer self-declaration for ordinary Class I; Notified Body required for Is, Im and Ir
Great Britain	Class I	Manufacturer conformity assessment and MHRA registration, subject to applicable UK requirements
United States	Class I	FDA General Controls; many, but not all, Class I devices are exempt from 510(k)
Australia	Class I	Manufacturer Declaration of Conformity and ARTG inclusion; special rules apply to sterile and measuring devices
Canada	Class I	Medical Device Establishment Licence obligations generally apply to importers/distributors; device licence normally begins from Class II
India	Class A	Lowest-risk category; licensing and registration requirements apply under Indian Medical Device Rules

Products That Must Not Be Included in Your Ordinary Class I Approval Scope

Do not approve these products under a simple Class I self-declaration procedure without additional classification review:

- Sterile Class I products — Class Is
- Products with a measuring function — Class Im

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- Reusable surgical instruments — Class Ir
- Powered therapeutic equipment
- Powered diagnostic equipment
- Patient-monitoring systems
- Ventilators and oxygen concentrators
- Infusion pumps
- Defibrillators
- Implantable devices
- Blood-contacting devices
- Long-term invasive devices
- Sterile syringes and needles
- Software providing diagnosis or treatment decisions
- Hyperbaric oxygen chambers used for treatment
- Pressure chambers intended to treat disease or injury
- Products administering medicinal gases
- Products sustaining or supporting life

Independent technical-documentation review and voluntary conformity assessment of non-sterile, non-measuring, non-reusable surgical Class I medical devices eligible for manufacturer self-declaration under Regulation (EU) 2017/745. The organization does not act as an EU Notified Body and does not issue statutory EU MDR certificates requiring Notified Body involvement.

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