CerviGuard MDR Class I Self-Assessment Declaration (Draft)

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MDR Class I Self-Assessment Declaration (Draft Proposal)

Document status: Draft proposal for internal legal/regulatory review
Version: 0.3-draft
Date: 2026-02-17
Scope: European Union (EU) and Romania
Product: CerviGuard

This document is not legal advice and is not a final regulatory declaration. Final content requires formal legal/regulatory approval before publication or external use.

1) Purpose

This draft captures a proposed manufacturer self-assessment declaration package structure for CerviGuard under Regulation (EU) 2017/745 (MDR), based on currently available project information in this repository and user-provided clarifications.

2) Manufacturer Identification

- Legal manufacturer name: SMARTCLOVER SRL
- Registered address: Strada Cernauti 17-21, Cluj-Napoca, Romania
- Country: Romania
- Registration data:
  - CUI (RO tax identifier): 50315196
  - ONRC registration number: J12/3050/2024
  - EUID: ROONRC.J12/3050/2024
- Contact email (regulatory/public): andreea@smartclover.ro
- Single Registration Number (SRN): Not assigned (as declared by manufacturer at this stage)

3) Device Identification

- Device/trade name: CerviGuard
- Device type: Software as a medical companion application (web platform)
- Current product form:

    - January 2020: first pilot as downloadable Win32 TensorFlow-based app (pre-launch of SMARTCLOVER SRL)
    - May 2025: online CerviGuard system launched
- Model/version identifier: CerviGuard v0.4.7 (retrieved from live login page footer on 2026-02-17)
- Basic UDI-DI: MISSING INPUT
- UDI-DI/UDI-PI: MISSING INPUT (or state not applicable if justified by regulatory owner)
- Intended market: EU and Romania
- First placing on the market date:
    - Downloadable pilot: January 2020
    - Online system: May 2025

4) Intended Purpose and User Profile

- Intended purpose: CerviGuard is positioned as a cervical cancer screening companion application that supports structured case intake, AI-assisted analysis, triage, and follow-up coordination, with clinicians retaining final decision authority.
- Target users: Authorized clinicians and authorized healthcare operations personnel.
- Target population/context: Individuals in cervical screening and follow-up pathways, including gynecological oncological prophylaxis management workflows.
- Core operational functions:
    - Secure role-based access
    - De-identified image/case intake
    - AI-assisted transformation-zone and lesion classification support
    - Case tracking and follow-up workflow support
    - CAEN context of manufacturer activity: 6201 - software development at customer request (corporate activity classification, not medical classification)
- Contraindications/limitations (draft IFU text):
    - Not intended for autonomous diagnosis or autonomous therapeutic decision-making.
    - Not intended to replace specialist clinical judgment, colposcopic examination, histopathology, or established national screening protocols.
    - Not intended for patient self-use or unsupervised operation by non-clinical users.
    - Outputs are decision-support indicators and must be interpreted by qualified clinicians in context with complete patient information.
    - Performance may be degraded with low-quality images, incomplete case metadata, or non-standard acquisition workflows.
    - Use is limited to authorized accounts and configured environments with data governance controls in place.
- Human oversight statement: CerviGuard is a companion support tool and not an autonomous decision-maker; final clinical judgment remains with qualified

professionals.

5) Classification Statement (MDR)

- Proposed class (manufacturer positioning): Class I
- Is device sterile: No (confirmation required from regulatory owner)
- Has measuring function: No
- Reusable surgical instrument: No
- Classification rule(s) applied (Annex VIII): Rule 11 (software), draft mapping to the "all other software" branch (Class I) subject to legal/regulatory confirmation
- Classification rationale summary: Draft legal rationale: CerviGuard is intended as a clinical companion workflow tool that structures case intake, supports triage prioritization, and provides non-binding AI-assisted signals under mandatory clinician oversight. It is not intended to independently establish diagnosis, select therapy, or trigger autonomous clinical action. Under this intended-use framing, classification is proposed under Rule 11 as Class I ("all other software"), with explicit reclassification trigger if future intended use expands toward direct diagnostic/therapeutic decision-driving functionality.

6) Conformity Route and Declaration Basis

- Conformity assessment route: Manufacturer self-declaration route intended for Class I positioning under MDR, subject to final regulatory confirmation.
- Technical documentation per Annex II and Annex III: MISSING INPUT
- GSPR conformity process per Annex I completed: MISSING INPUT
- Clinical evaluation documented: MISSING INPUT
- Risk management file documented and maintained: MISSING INPUT
- Post-market surveillance process implemented: MISSING INPUT

7) GSPR (Annex I) Conformity Summary

- GSPR checklist reference: MISSING INPUT
- Benefit-risk justification reference: MISSING INPUT
- Risk controls and residual-risk acceptance reference: MISSING INPUT
- Usability/human factors reference: MISSING INPUT
- Labeling/IFU reference: MISSING INPUT

8) Software Lifecycle, Validation, and Cybersecurity

- Software lifecycle procedure reference: MISSING INPUT
- Verification and validation summary reference: MISSING INPUT
- Cybersecurity posture statement: Current public wording is limited to "aligned with NIS2/CRA requirements." No certification claims are published.
- Cybersecurity controls reference: MISSING INPUT

- Vulnerability management process reference: MISSING INPUT
- Logging/traceability controls reference: MISSING INPUT
- Data protection controls reference: MISSING INPUT

9) Clinical and Performance Evidence

- Evidence timeline (publicly shareable):
  - January 2020: first CerviGuard pilot (Win32/TensorFlow, pre-launch of SMARTCLOVER SRL)
  - 2022: multiple projects and research tracks finalized
  - 2024: SMARTCLOVER SRL launched
  - May 2025: CerviGuard online system launched
  - 2025: partnership signed for TealGuard project
- Partnership statement approved for public use: "In 2025, SmartClover signed a partnership for the TealGuard project, focused on next-generation prophylaxis management for gynecological oncological pathologies."
- Quantitative KPI disclosure: not publicly available at this time
- Clinical evaluation report reference: MISSING INPUT
- Performance testing summary reference: MISSING INPUT
- Known limitations and safe-use conditions: MISSING INPUT
- Benefit-risk conclusion: MISSING INPUT

10) Post-Market Surveillance and Vigilance

- PMS plan reference: MISSING INPUT
- PMCF plan reference (if applicable): MISSING INPUT
- Incident reporting workflow reference: MISSING INPUT
- Corrective/preventive action workflow reference: MISSING INPUT
- Complaint handling process reference: MISSING INPUT

11) Draft Declaration Text

We, SMARTCLOVER SRL, acting as manufacturer, state under sole responsibility that CerviGuard is positioned as an MDR Class I medical device software companion application for EU and Romania, pending publication of finalized declaration identifiers and metadata.

Conformity substantiation is maintained within the manufacturer's technical documentation package and is to be finalized for formal declaration release after legal/regulatory approval.

12) Sign-Off (Pending Completion)

- Authorized signatory name: Andreea Damian
- Role/title: Founder and CEO

- Place: Cluj-Napoca, Romania
- Date: MISSING INPUT (signature date to be confirmed)
- Signature: _____

13) Internal Approval Checklist (Before External Publication)

- Regulatory review completed.
- Legal review completed.
- Clinical lead review completed.
- Security/privacy review completed.
- Product owner approval completed.
- Public redaction review completed (if public summary is published).

14) Public-Facing Interim Snippet

"CerviGuard is positioned as an MDR Class I medical device software companion application for EU and Romania. Detailed declaration identifiers and formal document metadata are being finalized for public release. Full substantiation is maintained in the manufacturer's technical documentation package."

15) Online Sources Used For This Draft

1. RisCo company profile:

- https://www.risco.ro/verifica-firma/smartclover-cui-50315196
- Data used: CUI, ONRC number, EUID, incorporation date, address, CAEN.

2. EU VIES REST API check (status snapshot):

- https://ec.europa.eu/taxation_customs/vies/rest-api/ms/RO/vat/50315196
- Note: response on 2026-02-17 returned `MS_UNAVAILABLE`; VAT-state validation could not be confirmed from that call at that time.

3. CerviGuard live login page:

- https://cerviguard.link
- Data used: visible app footer version (`CerviGuard v0.4.7`) captured on 2026-02-17.

16) Missing Information Required From SmartClover

1. UDI fields (or formal non-applicability rationale).
2. References/IDs for technical documentation, GSPR checklist, CER, risk management, PMS, PMCF, CAPA, incident, and complaint workflows.
3. Signature date for declaration sign-off.

4. Legal/regulatory approval of the draft Rule 11 Class I rationale text.