CareSterile – Caresoft CSSD Module: Scope of Work

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1. Overview & objectives

CareSterile (working name) is Caresoft's Central Sterile Services Department (CSSD) module: it tracks every reusable instrument and set from use, through decontamination and sterilization, back to the point of use — with full patient-level traceability. It follows the same product pattern as CareDine and CareIPC: standalone multi-hospital SaaS, optional Caresoft HIS integration, open APIs for other HIS, 3-level login, separate database per client hospital, and SEO/AEO/GEO marketing landing pages.

Target customers

Segment	Profile	What they need most
Large hospitals / chains	300–1,500+ beds, 10–40 OTs, central CSSD serving multiple sites	Multi-site CSSD, RFID/barcode tracking, machine integration, NABH/JCI audit readiness, loan-set and vendor management
Mid-size hospitals	100–300 beds, 3–10 OTs, single CSSD	Fast setup, barcode tracking, indicator logs, recall, simple reports
Hospitals on other HIS	Any size, existing HIS from another vendor	Standalone CSSD with API/HL7 link for patient, OT schedule and billing

Objectives

- Zero use of un-sterile or expired items: hard stop at issue if a load is not released or a pack is past expiry.
- Patient-level traceability: every sterilized set linked to load, cycle, operator, indicator result and patient/surgery.
- Recall in minutes: one click lists every pack and patient affected by a failed load.
- Accreditation-ready records for NABH, JCI and ISO 13485/17665-aligned processes, with no paper registers.
- Instrument life-cycle control: usage counts, repair, missing/damaged tracking and replacement planning.
- Cost visibility: cost per set, per cycle and per department chargeback.

The module shares masters (departments, users, patients, OT schedule) with CareIPC where both are deployed, so CSSD failures flow straight into infection surveillance.

2. Deployment & client-wise database architecture

Each client hospital (or hospital group) gets its own isolated database; one shared control database holds only tenants, subscriptions, licences and super-admin data. This gives data isolation for DPDP compliance, per-client backup/restore, and the option to host a large client's database on its own server or on-premise.

Database model

Database	Holds	Notes
Control DB (master)	Tenants, plans, licences, branches, super-admin users, DB connection map, global masters templates, audit of tenant actions	One per platform
Client DB (per hospital/group)	All CSSD masters, transactions, users, indicators, machine logs, reports	Auto-created from a template at onboarding; name like `cssd_<clientcode>`
Client DB — multi-site	Group hospitals with one central CSSD serving several units	One DB, `branch_id` on every transaction; central CSSD can serve satellite sites

Tenant routing

- Login resolves the tenant by sub-domain (`<client>.<product-domain>`) or client code, then connects to that client's DB.
- New client provisioning: create DB from template → seed default masters (departments, set types, cycle types, indicator types) → create hospital admin → send credentials by email/WhatsApp.
- Per-client settings: logo, colours, units, numbering formats, label templates, retention period, enabled features (RFID, machine integration, chargeback).

Deployment options

Option	For	Integration
Caresoft cloud (SaaS)	Mid-size hospitals, new clients	Caresoft HIS link or API to other HIS
Dedicated cloud DB/server	Large hospitals and chains	Same, with own backup schedule
On-premise	Hospitals with local-hosting policy	Same codebase; licence check against control DB
Embedded in Caresoft HIS	Existing Caresoft HIS clients	Single sign-on, shared patient/OT/billing masters

Backup & data handling

- Daily automated backup per client DB, 30-day point-in-time restore; restore one client without touching others.
- Data export per client on exit (Excel/CSV + PDF registers).
- Retention as per hospital policy; sterilization records default 10 years.

3. Three-level login & roles

Three login levels separate platform control, hospital control and daily CSSD work; within Level 3, role-based permissions decide screen and action access.

Level	Who	Can do
Level 1 — Super Admin (Caresoft)	Caresoft product, support and sales team	Create/suspend tenants, provision client DB, plans & licences, feature toggles, global master templates, platform health, support login (audited), landing-page leads
Level 2 — Hospital Admin	Hospital IT head, CSSD in-charge, Nursing Superintendent, Quality head	Users & roles, branches, departments/OTs, all CSSD masters, machine setup, label/print templates, approval rules, HIS integration settings, all reports

Level	Who	Can do
Level 3 — Department / Operational users	CSSD technicians, CSSD supervisor, OT/ward nurses, store, biomedical, infection control, management viewers	Day-to-day transactions as per role (below)

Level 3 roles (configurable)

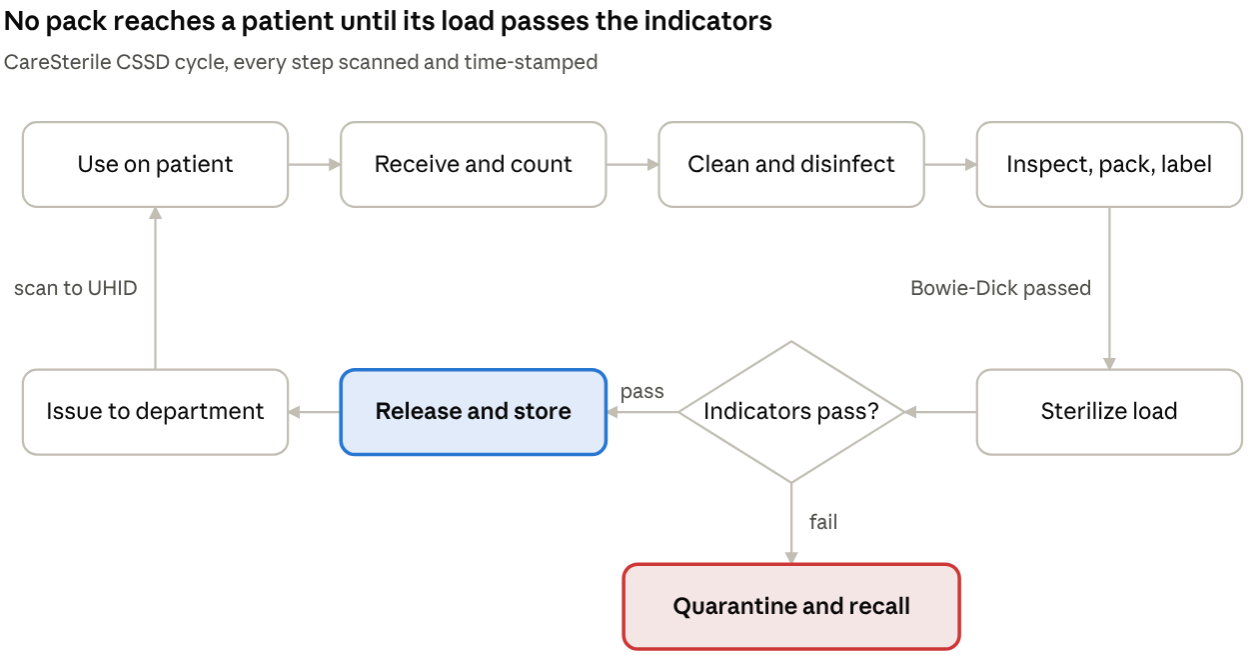
Role	Main permissions
CSSD Supervisor	Approve load release, failed-cycle actions, recall, discard/condemn, shift handover, all CSSD reports
CSSD Technician	Receive, decontaminate, inspect, pack, label, load, unload, store, issue
OT / Ward Nurse	Raise indent, view stock at CSSD, acknowledge receipt, return used sets, link set to patient/surgery
Store / Purchase	Consumables (pouches, indicators, detergents), instrument procurement, vendor loan sets
Biomedical Engineer	Machine master, PM/breakdown, Bowie-Dick and validation logs
Infection Control Nurse	View indicator failures, recall reports, CSSD audits (CareIPC link)
Management (view only)	Dashboards, KPIs, cost reports

Security

- Password policy, OTP/2FA for Level 1 and Level 2, optional for Level 3.
- PIN / barcode-badge quick login on CSSD floor terminals for gloved users.
- Session timeout, IP/device restriction per client, full audit trail (who, what, when, old/new value).
- Electronic sign-off on load release and recall (user + PIN), stored with timestamp.

4. Core functional modules

The module covers the full CSSD loop — indent, collection, decontamination, inspection, packing, sterilization, release, storage, issue, use on patient, return — plus masters, instrument life-cycle and consumables.



CSSD cycle · 8 steps, 1 release gate

A failed indicator quarantines the whole load and triggers recall for any pack already issued; only released packs can be scanned out to a department.

4.1 Masters

- Departments, OTs, wards, ICUs, cath lab, OPD procedure rooms, satellite sites (branch-wise).
- Instrument master: name, category, make/model, catalogue no., material, reprocessing instructions (IFU), max reuse cycles, unit cost, image.
- Individual instrument tracking (optional, large hospitals): unique ID, laser-etch/2D DataMatrix code, usage counter, repair history.
- Set/tray master: set composition with count per instrument, photo checklist, owning department, par level, standard turnaround time, cost per set.
- Pack types: tray, wrapped, pouch, container; shelf life by pack type and sterilization method (event-related or time-based expiry).
- Sterilizer master: steam autoclave, ETO, plasma (H_2O_2), dry heat, flash/IUSS; chamber size, cycle types and parameters.
- Washer-disinfector and ultrasonic cleaner master, with cycle types.
- Indicator master: Bowie-Dick, chemical (Class 1–6), biological; lot numbers and expiry.
- Consumables: pouches, wraps, tapes, indicators, enzymatic detergents, lubricants — with store link and reorder levels.
- Vendors and loaner companies; surgeons; surgery/procedure to set mapping (preference cards).

4.2 Indent & request

- Department indent for sets/items: routine, emergency (STAT) and OT-schedule-based auto-indent.
- Auto-indent from OT schedule (Caresoft HIS or other HIS): next-day surgeries pull mapped sets from preference cards.
- Par-level replenishment for wards/ICUs; indent approval rules; indent status tracking for the department.

4.3 Collection & receiving (dirty side)

- Pickup rounds by route and time; scan sets at department and at CSSD receiving.
- Count check against set composition; record missing, damaged, extra items with photo; auto-alert to department in-charge.
- Point-of-use pre-cleaning confirmation; high-risk/infectious flag (e.g. TB, prion-risk cases) for special handling.
- Patient/surgery link carried from OT so used-set history is traceable.

4.4 Decontamination & cleaning

- Manual cleaning log: detergent, dilution, contact time, operator.
- Ultrasonic and washer-disinfector loads: scan sets into a load, cycle no., parameters, pass/fail, printout or machine data capture.
- Washer efficacy tests (protein residue/soil test) logged daily.

4.5 Inspection, assembly & packing (clean side)

- Guided assembly: on-screen checklist with photos and counts per set; magnifier inspection result per instrument.
- Replace missing/damaged items from spares; send instrument to repair with reason.
- Choose pack type, add internal chemical indicator, print barcode/QR label: set name, set ID, pack date, sterilizer, load no., expiry, packer, checker.
- Double sign-off (packer + checker) for critical sets.

4.6 Sterilization

- Daily machine readiness: warm-up, leak test, Bowie-Dick test — machine blocked for the day until Bowie-Dick passes.
- Load building: scan packs into a load; system checks compatibility (e.g. no heat-sensitive item in steam load), chamber capacity and cycle type.

- Cycle record: start/end time, temperature, pressure, exposure time, operator; manual entry or auto-capture from machine (USB/serial/network, where supported).
- External chemical indicator and biological indicator per load as per policy (BI mandatory for implant loads and ETO).
- Load release: supervisor approves after parameters and indicators pass; implant loads held until BI result (with documented early-release override).
- Failed cycle: auto-quarantine of all packs, reason, re-process workflow, and recall trigger if any pack already left CSSD.

4.7 Sterile storage & stock

- Rack/shelf location by scan; FIFO and expiry-based picking.
- Expiry alerts (7/3/1 days) and auto-move of expired packs to re-process.
- Live stock by set, department and location; par-level dashboard.

4.8 Issue, use & return

- Issue against indent by scan; hard stop if pack not released, expired, wrong set or package damaged.
- Delivery acknowledgement by department (scan + PIN).
- Use on patient: OT nurse scans pack to patient UHID/IP no. and surgery — from HIS or standalone screen; pack label stickers for patient file.
- Return of unused packs (re-shelve if intact and in date) and used sets back to the dirty cycle.

4.9 Recall

- Recall by load, sterilizer, date range, indicator lot or set.
- System lists every affected pack with current location: in store, issued to department, or used on patient (with patient and surgeon names).
- Recall task list, department notifications, closure with remarks; recall report for infection control and quality.

4.10 Instrument life-cycle & loan sets

- Usage count per instrument/set; alert near max reuse cycles.
- Repair and vendor return tracking; condemnation with approval; replacement requests to purchase.
- Loaner/vendor sets (orthopaedic implants etc.): receive from vendor, inventory check, process, link to patient, return to vendor with document trail.

4.11 Consumables & costing

- Consumption of pouches, wraps, indicators and detergents per load/set.
- Cost per set cycle = consumables + utilities + manpower share + instrument depreciation (configurable).
- Department-wise chargeback and patient billing of CSSD charges where policy applies (posted to HIS billing).

5. Quality, compliance & traceability

Every pack carries a digital history from receiving to patient, and every paper register a CSSD keeps today is replaced by a system record that prints in audit format.

Traceability chain

Instrument / set → receiving (who, when, from where, which patient) → cleaning load → inspection & packing (packer, checker) → sterilizer, load, cycle, indicators → release (who approved) → storage location → issue (to whom) → patient UHID & surgery → return.

Identification options

Option	Best for	Hardware
Barcode / QR labels on packs	All hospitals (default)	Label printer, handheld or fixed scanners
2D DataMatrix on instruments	Large hospitals tracking single instruments	Laser-etch (vendor), 2D imager scanner
RFID tags on trays/containers	Large hospitals, high volume	RFID reader at receiving, store and OT exit

Compliance support

- NABH: CSSD-related standards on sterilization, infection control and records (registers, indicator logs, recall, training records) mapped to reports.
- JCI: traceability, sterilization monitoring, recall and staff competency evidence.
- Process alignment with ISO 17665 (moist heat), ISO 11135 (ETO), ISO 15883 (washer-disinfectors) record-keeping — the software records evidence; the hospital remains responsible for validation.
- Daily registers auto-built: Bowie-Dick register, autoclave register, BI register, ETO register, washer log, recall register, expiry discard register.
- Staff competency and training log per CSSD staff; SOP library with version control and read-acknowledgement.

- CSSD internal audit checklists (daily/weekly/monthly) with scoring and corrective action (CAPA) tracking.
- Environmental logs: temperature and humidity of sterile store, pressure differentials (manual entry or IoT sensor).

Audit trail

- Every create/edit/delete with user, time, old and new value; no hard delete of sterilization records.
- Locked records after load release; corrections only by addendum with reason.

6. Integrations, notifications & reports

Integrations

System	Data exchanged	Method
Caresoft HIS	Patients (UHID/IP), OT schedule, surgeons, departments, users (SSO), CSSD charges to billing, consumables from pharmacy/store	Native DB/API link
Other HIS	Same as above	REST API + HL7 v2 (ADT, SIU) / FHIR where available; CSV import fallback
CareIPC (infection control)	Failed loads, recalls, patients exposed, CSSD audit scores	Native link
Store / inventory (Caresoft or other)	Consumable indents and issues, instrument purchase	API
Sterilizers & washers	Cycle parameters and printouts	Machine data port / network / file pickup (model-dependent)
Label printers, scanners, RFID	Labels, scans	Zebra/TSC ZPL, HID scanners, RFID SDK
WhatsApp & email	Alerts, reports	Caresoft WhatsApp platform, SMTP/SES
ABDM (optional)	Procedure linkage on patient record	Via HIS

Notifications

- Bowie-Dick or cycle failure → CSSD supervisor, biomedical, infection control (app + WhatsApp).
- BI positive → instant recall alert to CSSD, ICN, OT in-charge, quality head.
- Expiry due, par level below minimum, indent delayed beyond turnaround time.
- Missing/damaged instrument at receiving → department in-charge.
- Machine PM due, indicator/consumable stock low, loan set due for return.

Dashboards

- CSSD live board (TV display): sets in each stage, loads running, pending indents, STAT requests.
- Management dashboard: throughput, turnaround time, failures, recalls, cost, department usage.
- Department view: my indents, my stock, ETA.

Standard reports (40+, Excel/PDF)

Area	Reports
Operations	Daily production, set-wise turnaround time, pending indents, department-wise issues, shift handover
Sterilization	Autoclave/ETO/plasma registers, load details, cycle failure analysis, machine utilisation
Quality	Bowie-Dick, BI and CI registers, recall register, audit scores, CAPA status, NABH/JCI evidence pack
Traceability	Pack history, patient-wise sets used, set-wise patient list, loan set trail
Instruments	Missing/damaged, repair, near end-of-life, condemned, inventory valuation
Cost	Cost per set/cycle, consumable usage, department chargeback

KPIs tracked: turnaround time vs standard, cycle failure %, BI positive rate, recall count, missing instrument rate, expired-pack rate, machine uptime, cost per set.

7. Marketing landing pages — SEO, AEO & GEO

A lead-generating marketing site, same pattern as CareDine and CareIPC: product pages built to rank on Google (SEO), be quoted in answer boxes and voice search (AEO), and be cited by AI assistants such as ChatGPT, Gemini and Perplexity (GEO).

Pages

Page	Purpose / target query
Home — CSSD management software	"CSSD software India", "hospital sterilization tracking software"
Features	Instrument tracking, sterilization monitoring, recall, NABH registers
For large hospitals & chains	Multi-site CSSD, RFID, machine integration
For mid-size hospitals	Quick setup, barcode tracking, affordable SaaS
Works with any HIS	Caresoft HIS + other HIS integration
NABH / JCI CSSD compliance	"NABH CSSD requirements", checklists, register formats
Use-case pages	Recall management, loan set tracking, OT set planning, Bowie-Dick logs
Pricing / plans	Plan comparison, request quote
Resources / blog	CSSD SOP guides, instrument tracking guides, sterilization indicator explainers
FAQ hub	30+ question-answer pairs
Book a demo / contact	Lead form, WhatsApp click-to-chat
Regional pages	Country/city pages for India, Middle East, Africa (international sales)

SEO

- Keyword map per page; clean URLs, title/meta, H1–H3 structure, internal linking.
- Core Web Vitals: fast load, mobile-first, compressed images, lazy loading.
- XML sitemap, robots.txt, canonical tags, Open Graph and Twitter cards.
- Schema: Organization, SoftwareApplication, Product, FAQPage, HowTo, BreadcrumbList, Article.
- Google Search Console and Analytics (GA4) set-up.

AEO (answer engine optimisation)

- Each page opens with a 40–60 word direct answer to its main question.
- FAQ blocks with FAQPage schema; "What is…", "How to…" and comparison tables.
- Voice-search phrasing ("which software tracks surgical instruments in hospitals").

GEO (generative engine optimisation)

- `llms.txt` and an AI-readable product fact sheet (features, integrations, certifications, client count).
- Entity-consistent facts across pages: Caresoft, 1,000+ hospitals, 12+ countries, CMMI Level 5, ISO 27001.
- Citable content: statistics-backed guides, definitions, step-by-step CSSD process pages with clear headings.
- Author/expert bylines and dated updates for trust signals.

Lead generation

- Demo request form (name, hospital, beds, OTs, current HIS, city, phone, email) → Level 1 admin lead list + email/WhatsApp alert to sales.
- Downloadables gated by email: NABH CSSD checklist, CSSD register formats, ROI calculator.
- Lead status tracking (new, contacted, demo done, proposal, won/lost) and CRM export.

8. Tech stack, NFRs, phases & boundaries

Tech stack (to align with CareDine / CareIPC builds)

- Backend: PHP 8 + MySQL 8, one DB per client + control DB; REST APIs (JWT) for HIS and mobile.
- Frontend: responsive web, touch-friendly CSSD floor screens (large buttons, scan-first), PWA for nurses' handhelds.
- Printing: ZPL/browser label printing; PDF registers.
- Hosting: Caresoft cloud (Linux), SSL, daily backups; on-premise package for large clients.
- Languages: English first; Hindi/Marathi UI labels for floor staff (as done in CareDine).

Non-functional requirements

Area	Requirement
Performance	Scan-to-response under 1 second; 500+ concurrent users per large client
Availability	99.5% uptime on cloud; offline scan buffer on floor terminals that syncs when back online
Security	DPDP-aligned consent and data handling, role-based access, encryption in transit (TLS) and at rest for backups, OWASP Top-10 checks
Scalability	Add a client DB without downtime; multi-site under one client
Auditability	Immutable sterilization records, full audit trail, 10-year retention default
Usability	Max 3 taps/scans for any floor transaction; works with gloves (scan/PIN login)

Phase plan

Phase	Scope	Output
0 — Foundation	Control DB, client DB provisioning, 3-level login, roles, masters, marketing site + lead form	Tenant onboarding live, landing pages indexed
1 — Core CSSD cycle	Indent, receiving, cleaning, packing, labels, sterilization, load release, storage, issue, return	Barcode-based CSSD running end to end
2 — Quality & recall	Indicators (BD/CI/BI), failed cycle, recall, registers, audit checklists, CAPA, SOP library	NABH-ready records
3 — Integrations	Caresoft HIS native link, other-HIS API/HL7, CareIPC link, patient linkage, billing, WhatsApp/email alerts	Patient-level traceability
4 — Large-hospital features	Multi-site central CSSD, instrument-level 2D tracking, RFID, machine data capture, loan sets, costing & chargeback	Enterprise edition

Phase	Scope	Output
5 — Analytics & content	Dashboards, TV board, 40+ reports, KPIs, SEO/AEO/GEO content expansion, regional pages	Sales-ready product + demo hospital

Deliverables

- Working multi-tenant web application with source code, DB scripts and client-DB template.
- Marketing website with SEO/AEO/GEO set-up and lead management.
- API documentation for other-HIS integration.
- Demo hospital with sample data; user manuals per role; admin and deployment guide; training videos.

Out of scope

- Sterilizer, washer, RFID or printer hardware supply.
- Laser etching of instruments (vendor service).
- Physical validation/qualification of sterilizers (IQ/OQ/PQ) — software only records results.
- Machine integration for models with no data port or vendor protocol.

Assumptions & open points

- Product name "CareSterile" is a working name — to confirm.
- Stack shown is assumed to match CareDine/CareIPC — confirm before build.
- Pricing model (per bed, per OT, per site or flat SaaS) to be decided.
- List of sterilizer/washer brands to integrate first to be shared by sales/biomedical.