27th WFHSS CONGRESS - 2026 -

BELGRADE

21ST - 24TH OCTOBER 2026

USDS

WFHSS World Federation for Hospital Sterilisation Sciences

Strategic Role of the Central Sterile Services Department in Personalised Medicine

Validation, Protocols and ISO 13485 Certification in a Hospital-Based Manufacturer of Custom-Made Devices

Susana Gómez De Los Infantes · Biomedical Design Engineer
Xiomara Hernández · Surgical Nurse, UPAM3D

Hospital General Universitario Gregorio Marañón · Madrid, Spain
One of the largest public hospitals in Spain, with more than 1200 beds and over 8000 professionals

SaludMadrid · Hospital General Universitario Gregorio Marañón · Comunidad de Madrid · UPAM3D PLAN & FAB

BELGRADE
21ST - 24TH
OCTOBER 2026

Disclosure of Interests

Collaboration with **Antonio Matachana S.A.** · Testing at the Matachana Test Center (**MATEC**)

No personal financial compensation was received.

Funded by ISCIII · CSIC (PTI FAB3D) · UPM Health Tec Innovation Hub

PT23/00116 · PI25/01469

The authors declare no conflict of interest.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

whss World Federation for Hospital Sterilisation Sciences

Presentation Structure

A joint presentation from engineering and nursing

PART 1 · 16 MINUTES

The Hospital as Manufacturer

- **UPAM3D** — from FabLab to certified manufacturer
- What we **do**
- **Regulatory** framework
- The **ecosystem**
- Our **validation** strategy

Susana Gómez de los Infantes

PART 2 · 12 MINUTES

The CSSD and Sterilisation

- How we **tested** it
- What we **found**
- **Material behaviour**
- Four **critical control points** for the CSSD
- The **CSSD workflow**, **traceability** and **conclusions**

Xiomara Hernández

UPAM3D — Who We Are

Advanced Planning and 3D Manufacturing Unit · Hospital Gregorio Marañón

2015	1st	I – IIb	2,400+
Unit founded as a hospital FabLab	Public hospital in Spain certified to ISO 13485	Device classes under manufacturing licence	Clinical cases managed to date

EVERY PATIENT IS DIFFERENT, AND CONVENTIONAL SURGICAL SOLUTIONS ARE NOT ALWAYS ENOUGH

Manufacturing licence 2020 · UPAM3D formalised 2021 · Class IIb 2023, first in Europe in-house · Premio QIA 2023

BELGRADE
21ST - 24TH
OCTOBER 2026

A COMPLETE MEDICAL DEVICE MANUFACTURING WORKFLOW INSIDE A HOSPITAL

Clase I



Clase IIa



Clase IIb



27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

WFHSS World Federation for Hospital Sterilisation Sciences

What We Design and Produce

Three service lines, one integrated digital workflow

Biomodels & Anatomical Replicas

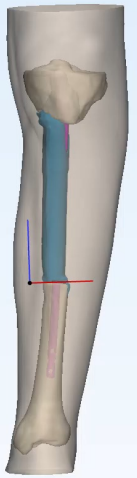
Patient-specific anatomical models generated from CT and MRI imaging. Used for surgical rehearsal, patient consent and resident training.

Advanced 3D Surgical Planning

Virtual osteotomy planning, implant positioning and augmented reality overlays. Reduces intra-operative decision-making and operating time.

Patient-specific surgical guides and implants

Class I to IIb, manufactured under our own ISO 13485 quality management system.



What We Design and Produce

Three service lines, one integrated digital workflow

Biomodels & Anatomical Replica

Patient-specific anatomical models generated from CT and MRI imaging. Used for surgical rehearsal, patient consent and resident training.

Advanced 3D

Virtual osteotomy planning, implant positioning and augmented reality overlays. Reduces intra-operative decision-making and operating time.

Patient-specific surgical d implants

Class I to IIb, manufactured under our own ISO 13485 quality management system.

ABOUT **TURNING CLINICAL NEEDS** INTO **SAFE, PERSONALIZED SOLUTIONS** AND BRINGING **NEW TECHNOLOGIES INTO CLINICAL PRACTICE**


SaludMadrid
Hospital General Universitario
Gregorio Marañón

The Regulatory Framework

What it means for a hospital to become a legal manufacturer

MDR 2017/745

- A quality management system
- No equivalent device on the market
- Documented design, manufacture and use
- Review of experience and corrective action

ISO 13485:2016

Certified quality management system

- Design control and design history files
- Supplier and material qualification
- Process validation — including sterilisation
- Traceability, vigilance and follow-up

Sterilisation is a special process

Its result cannot be verified by inspecting the finished device — it must be validated.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

WFHSS World Federation for Hospital Sterilisation Sciences

A Multidisciplinary Ecosystem

The unit works because every stakeholder has a defined role

- Surgeons & Clinicians
- Radiology
- Biomedical Engineers
- Research Institute

UPAM3D
Point-of-Care Hub

- **CSSD Sterile Services**
- Hospital Management
- Industry Partners
- Regulatory & Quality

Governance: Management Board · Clinical Services · Engineering · Pharmacy · CSSD · Legal & Regulatory

Setting the Scene

Why Custom-Made Devices change everything for the CSSD

Point-of-Care 3D Printing

Hospitals are no longer only users of medical devices — they have become manufacturers.

Custom-Made Devices

One patient. One procedure. One device. There is no batch, no backup and no replacement. Loss or contamination means the surgery is cancelled.

The CSSD Challenge

PLA, ASA and biocompatible resins are thermolabile. Steam sterilisation destroys them. An alternative had to be found, validated and documented.

Objectives

1 **Validate VH_2O_2 sterilisation**

For 3D-printed CMDs in PLA, ASA and biocompatible resins, targeting SAL 10^{-6}

2 **Identify critical process variables**

Device geometry, organic soil and post-process material integrity

3 **Design and implement CSSD protocols**

Decontamination, drying, packaging, sterilisation and unique traceability

4 **Demonstrate regulatory compliance**

MDR 2017/745 Article 5.5 and ISO 13485:2016 certification

Objectives

1 **Validate VH_2O_2 sterilisation**

For 3D-printed CMDs in PLA, ASA and biocompatible resins, targeting SAL 10^{-6}

2 **Identify critical process variables**

Device geometry, organic soil and post-process material integrity

3 **Design and implement CSSD protocols**

Decontamination, drying, packaging, sterilisation and unique traceability

4 **Demonstrate regulatory compliance**

MDR 2017/745 Article 5.5 and ISO 13485:2016 certification

A SAFE, CONTROLLED AND REPEATABLE PROCESS THAT
WE COULD USE IN OUR **DAILY CLINICAL PRACTICE**

How We Validated It

Four sequential blocks · material first, microbiology last

01

Material compatibility

Sterilise the polymer and check it survives the cycle

02

Dimensional comparison

Scan the same piece before and after processing

03

Functional fit

Check the guide still seats on the anatomy as designed

04

Microbicidal efficacy

Only then: inoculate spores and measure the reduction

There is no point proving a process is sterile if the device no longer works.

Block 04 used a half-cycle programme — one or two of the four VH_2O_2 injections. Validation is performed on a fraction of the cycle: if the process works there, the full clinical cycle carries the margin above it.

27th WFHSS CONGRESS - 2026 -
BELGRADE
21ST - 24TH OCTOBER 2026

Does Sterilisation Change the Device?

Dimensional and functional validation after two consecutive VH_2O_2 cycles

Biomodel–guide fit test

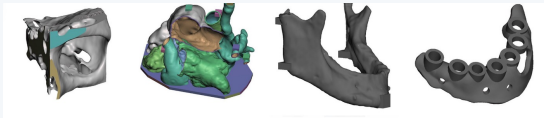


Before sterilisation



After two cycles

The surgical guide seats on the mandible identically before and after processing.



Multispectral CT, cone-beam CT and structured-light scanning

Visual inspection
No discoloration or deformation

Dimensional inspection
Mean absolute error 0.21 → 0.24 mm

Fit test
No change in guide seating

Below the resolution of medical imaging

Dimensional validation with Matachana · RAPID cycle, 130HPO®

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

wfhss World Federation for Hospital Sterilisation Sciences

The Bridge Between Innovation and the Patient

INNOVATION

Design · 3D printing
New materials
Complex geometries

▸

STERILISATION

CSSD

Process validation
Standardised protocols
Traceability · Risk control

▸

PATIENT

Sterile · Traceable
Regulatory compliant
Delivered to theatre

No sterilisation, no surgery. The CSSD does not end the manufacturing process — it completes it.

Handover · Susana → Xiomara

BELGRADE
21ST - 24TH
OCTOBER 2026

PART 2

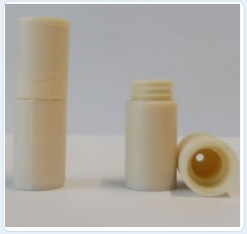
The CSSD and the Validation of VH_2O_2 Sterilisation

Xiomara Hernández · Surgical Nurse, UPAM3D

DOES THE PROCESS REACH THE MICROORGANISM?

How We Tested It

1 Test specimens



Open lumen

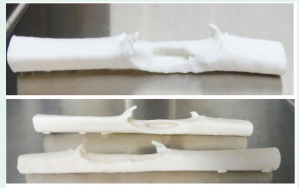


Sealed cavity

2 Real clinical devices



Surgical guides



Bone-replica biomodels

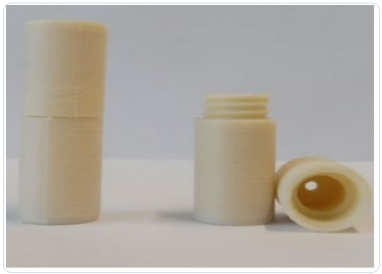
Anatomically complex bone replicas, selected as the worst case

Half-cycle validation: one or two of the four VH_2O_2 injections of a full RAPID programme.

130HPO®	10^6 CFU	*G. stearothermophilus* ATCC 7953	SAL 10^{-6}
Matachana steriliser	inoculated per specimen	biological indicator · pure strain	the target

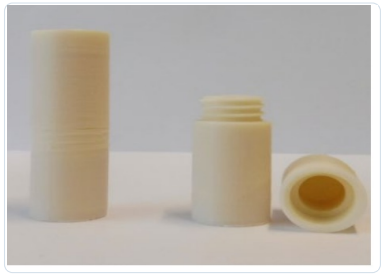
PLA — ASA — BIOMED CLEAR RESIN

What We Found



OPEN

11.4



SEALED

1.6

Surfaces

Zero spores recovered.
All three materials.

Open cavities

The agent reaches inside.
Process works.

Sealed cavities

The agent does not arrive.
Process fails.

**It is not the material.
It is the geometry.**

Material Behaviour — Open vs Sealed

THESE ARE VALUES EXTRAPOLATED FROM THE HALF CYCLE, NOT MEASURED LOG REDUCTIONS

Material	Open no protein	Open + protein	Sealed no protein	Sealed + protein
PLA	10.0	10.2	7.0	8.0
ASA	11.4	10.6	1.6	1.6
BioMed Clear Resin	11.2	6.3	4.4	4.0

PLA

Chemically permeable

Its fibrous structure holds VH_2O_2 and degrades, using up the agent before the core.

ASA

A physical barrier

Strongly hydrophobic. Blocks the sterilant from entering the cavity.

Protein soil

A double interferent

Consumes VH_2O_2 and shields the spores. BioMed Clear: 11.2 → 6.3 log.

Where recovery controls did not reach 10^6 CFU, SAL 10^{-6} cannot be formally claimed (ISO 11138-1 · ISO 14937).

Four Critical Control Points for the CSSD



1

Pre-cleaning

Protein soil is the main interferent. No sterilisation method compensates for inadequate cleaning. Protocols must be device-specific and validated (ISO 15883-5).



2

Device Geometry

Open geometries are safe; sealed cavities are high risk. The CSSD must be consulted at the design stage — before printing, not after.



3

Traceability

A unique CMD Serial Number from prescription to OR, integrated into the patient record..



4

Risk Management

CMDs are irreplaceable — no batch, no backup. Formal risk assessment under ISO 14971 for every device category.

The CSSD Workflow

Standardised, documented and auditable under ISO 13485

1	2	3	4	5	6	7
Prescription	**Design & print**	**Decontamination**	**Drying**	**Packaging**	**Sterilisation**	**Delivery**
Serial Number assigned	FDM / SLA	ISO 15883-5	Controlled cabinet	Double Tyvek®	130HPO® STANDARD	Sterile, to OR

Zero
logistical errors recorded

Every
Devices tracked

Workflow
Seif and reproducible

Conclusions

VH_2O_2 is effective for Class I devices and surgical guides

SAL 10^{-6} derives from half-cycle testing extrapolated to the full cycle — the recognised validation design. Implantable devices are outside this scope.

Geometry and organic soil are the critical determinants

Open geometries and clean surfaces are safe. Sealed cavities and protein contamination create failure risk.

The CSSD is a strategic, not merely operational, partner

In the hospital-manufacturer model the CSSD validates, certifies and completes the manufacturing process.

Every centre must validate its own materials and cycles

STANDARD is a manufacturer's programme name, not an industry category: there is no construction standard for VH_2O_2 equipment. Validate your own cycles — as for steam and LTSF.

Public-private collaboration made this possible

Research continues: PCL, PEEK, silicone, peroxide residue studies and biocompatibility testing to extend the validated scope.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

Thank You

Questions & Discussion

Susana Gómez de los Infantes ·
Biomedical Design Engineer ·
s.gomezdelosinfantes@gmail.com

UPAM3D

Xiomara Hernández · Surgical Nurse ·
xiomara.hernandez@salud.madrid.org



UPAM3D — 3D Manufacturing Unit



Central Sterile Services Department

SaludMadrid
Hospital General Universitario Gregorio Marañón
Comunidad de Madrid

matachana