

CELTIC Proposers Day

in Leuven on 25.09.26



SUCCESSFUL SME

Taner Gülez

Manager, Artech International, Brussels

www.celticnext.eu



Turning EU regulation into market access

Artech International: a Brussels SME between EU rule-making
and the companies that must live with it

The Challenge

&

The Solution

Every EU rule is a wall for outsiders. We build the door.

Artech International | Brussels | founded 2019 | 10+ staff |
>1 M€/year revenue

How EU rules reach beyond EU borders

- **Inside the EU**

- One market, one rulebook: AI Act, GDPR, ESPR and the Digital Product Passport, MDR
- Member states implement; delegated acts and standards take years
- Written for the single market, but the market is not closed

- **Outside the EU**

- Sell a product, run a service or build technology for EU users and you inherit the obligations
- Long timelines, dense texts, 27 national authorities
- Most non-EU SMEs meet the rules at the border, when it is already expensive

What Artech does

In EU-funded projects

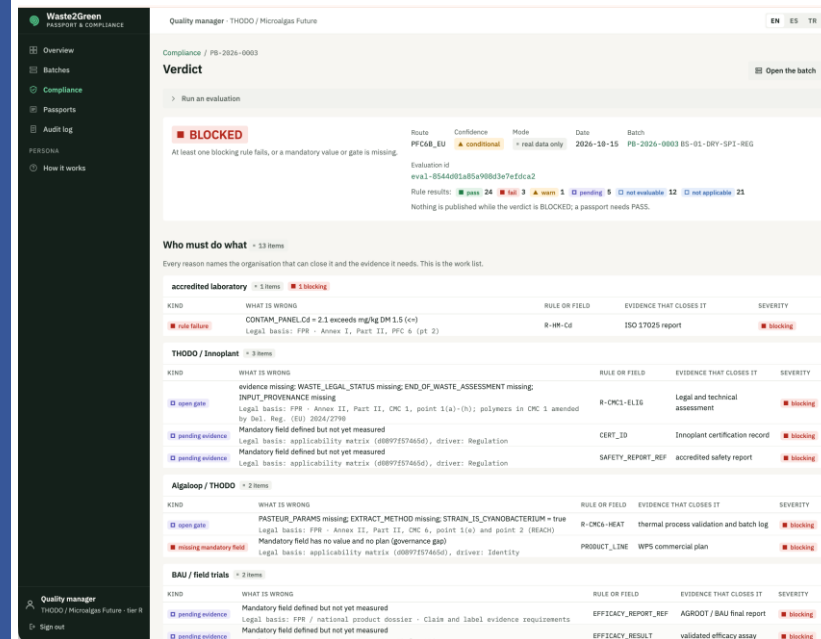
- Coordinator and partner in CELTIC, Chips JU, Horizon Europe and EU-India consortia
- Compliance built into the work plan: **AI Act, GDPR, DPP as deliverables, not afterthoughts**
- **Prototypes tested under the new rules, then taken to market**



In the market

- Advisor to non-EU companies entering the EU: readiness, documentation, entry plan
- AI Act, GDPR and DPP as service lines; **BeyondBarCode**, our DPP platform, built from EU project know-how
- Sold outside the EU, revenue and know-how brought back to Brussels

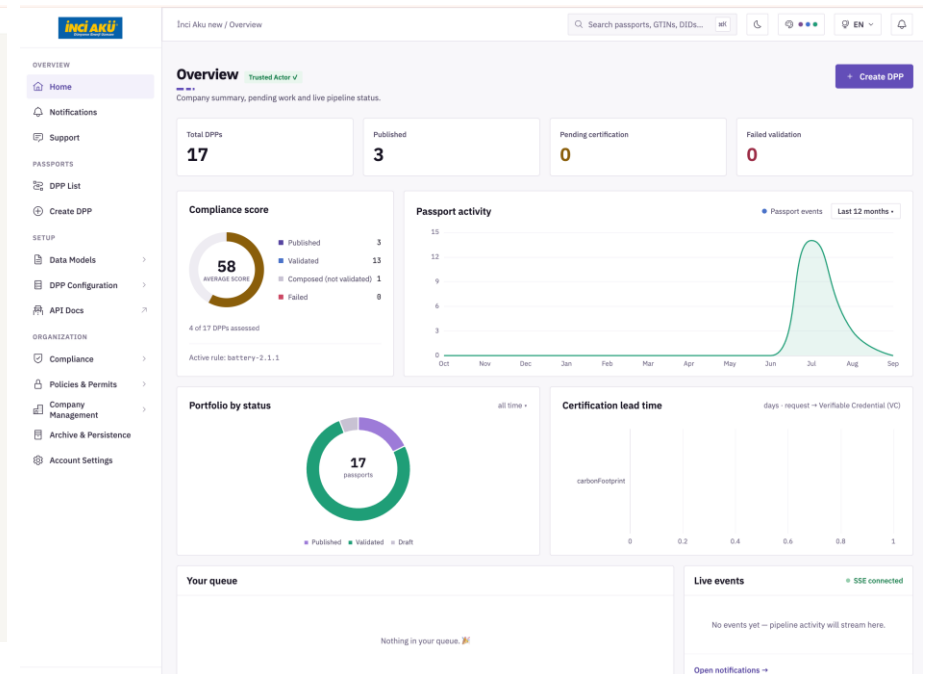
Know-how turned into product



The screenshot shows the 'Quality manager' interface for 'THODO / Microalgae Future'. It displays a 'Verdict' section with a 'BLOCKED' status, indicating a rule failure. Below this, it lists 'Who must do what' with a table of issues. The table has columns for 'KIND', 'WHAT IS WRONG', 'RULE OR FIELD', 'EVIDENCE THAT CLOSSES IT', and 'SEVERITY'. Issues include 'accredited laboratory', 'THODO / Innoplant', 'Algaloop / THODO', and 'BAU / field trials'.

KIND	WHAT IS WRONG	RULE OR FIELD	EVIDENCE THAT CLOSSES IT	SEVERITY
rule failure	CONTAM_PANEL.Cd = 2.1 exceeds mg/kg DM 1.5 (c=)	R-HR-Cd	ISO 17025 report	blocking
open gate	evidence missing: WASTE_LEGAL_STATUS missing: END_OF_WASTE_ASSESSMENT missing: INPUT_PROVENANCE missing	R-ORCS-ELIS	Legal and technical assessment	blocking
pending evidence	Mandatory field defined but not yet measured	CERT_ID	Innoplant certification record	blocking
pending evidence	Mandatory field defined but not yet measured	SAFETY_REPORT_REF	accredited safety report	blocking
open gate	PASTEUR_PARAMS missing: EXTRACT_METHOD missing: STRAIN_IS_CYANOBACTERIUM = true	R-ORCS-HEAT	thermal process validation and batch log	blocking
missing mandatory field	Mandatory field has no value and no plan (governance gap)	PRODUCT_LINE	WPS commercial plan	blocking
pending evidence	Mandatory field defined but not yet measured	EFFICACY_REPORT_REF	AGROOT / BAU final report	blocking
pending evidence	Mandatory field defined but not yet measured	EFFICACY_RESULT	validated efficacy assay	blocking

Regulatory compliance tool + DPP
Waste Water Treatment



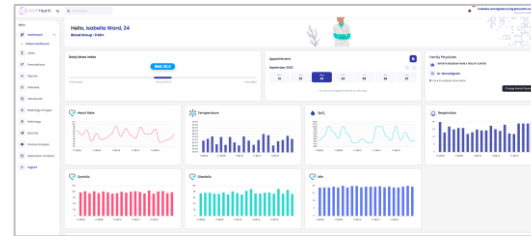
The screenshot shows the 'Overview' page of the 'Battery DPP Platform'. It displays a summary of DPPs (Total DPPs: 17, Published: 3, Pending certification: 0, Failed validation: 0). It includes a 'Compliance score' of 58 and a 'Passport activity' chart showing a peak in July. The 'Portfolio by status' shows 17 passports (Published, Validated, Draft). The 'Certification lead time' chart shows a peak in July. The 'Your queue' section shows 'Nothing in your queue'.

Battery DPP Platform - Commercialized

and many more...

Three countries, one platform

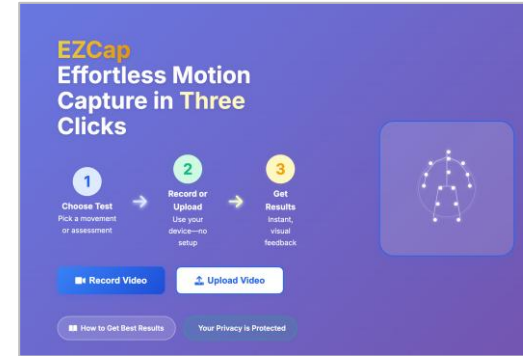
Three use cases, one login, one patient record. Artech made them talk to each other.



Türkiye

Rasyotek/Rasyomed, Karel, Kafein

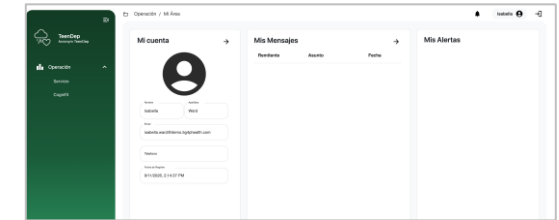
Hospital platform as the hub; ward positioning and environmental sensing; cybersecurity assessment



United Kingdom

Essex, Metrar, Brunel

AI motion analysis from a phone video, real-patient pilot at Colchester hospital



Spain

IDAvinci, Horus ML

Adolescent depression screening from voice and cognitive tests, the highest-risk AI system in the project



Artech in 5G4PHealth: Health Wallet and regulatory compliance

Coordinator of 11 partners, and owner of two work items that outlive the project.

Health Wallet

Patient-held record across three countries: one login, one identity, data shared only with consent. eIDAS-ready, on the shared data layer linking TR, UK and ES services.

Regulatory compliance

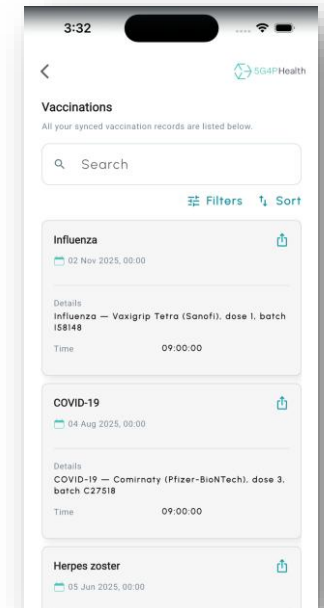
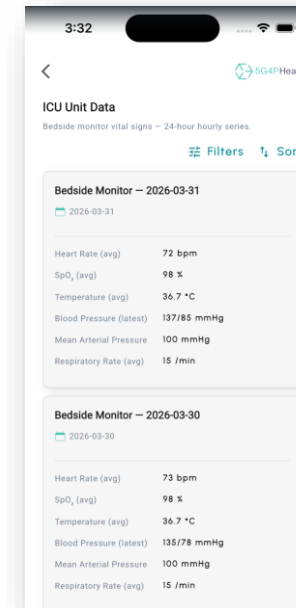
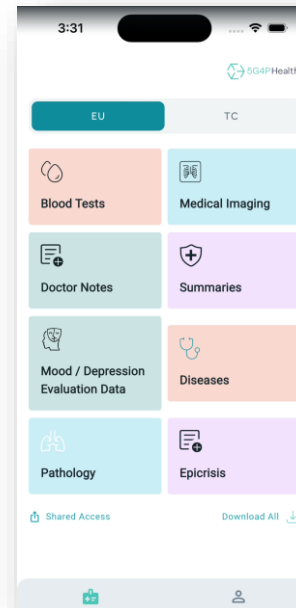
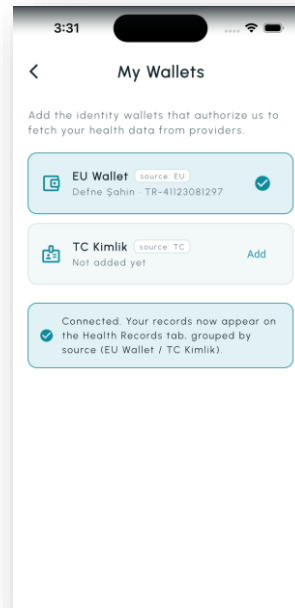
Real AI systems, real patients: the AI Act tested in practice, not in theory.

Partner information form with the legal basis under every question

AI inventory and risk classification for 9 systems (Art. 6, Annex I and III)

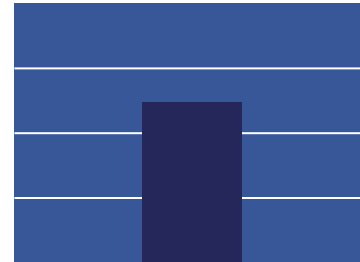
Templates for data governance, human oversight, Annex IV documentation, incident flow and transparency notices

GDPR: consent flows, retention rules and DPIA requirements agreed across BE, TR, UK and ES

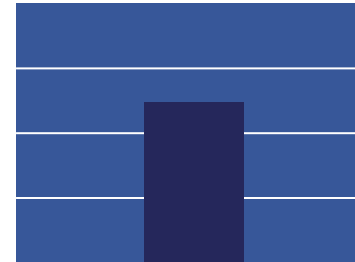


Every market has its wall

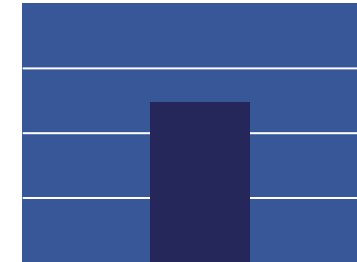
The EU is one case of a global pattern. The method we learned here works at every border.



United States
 FDA, FCC, UL
 state privacy laws



China
 CCC, PIPL
 cybersecurity review



India
 BIS, DPDP
 sector registrations



UK and Gulf
 UKCA, UK GDPR
 SASO, G-mark

Same four layers everywhere: safety and certification | data and privacy | sustainability and traceability | sector rules

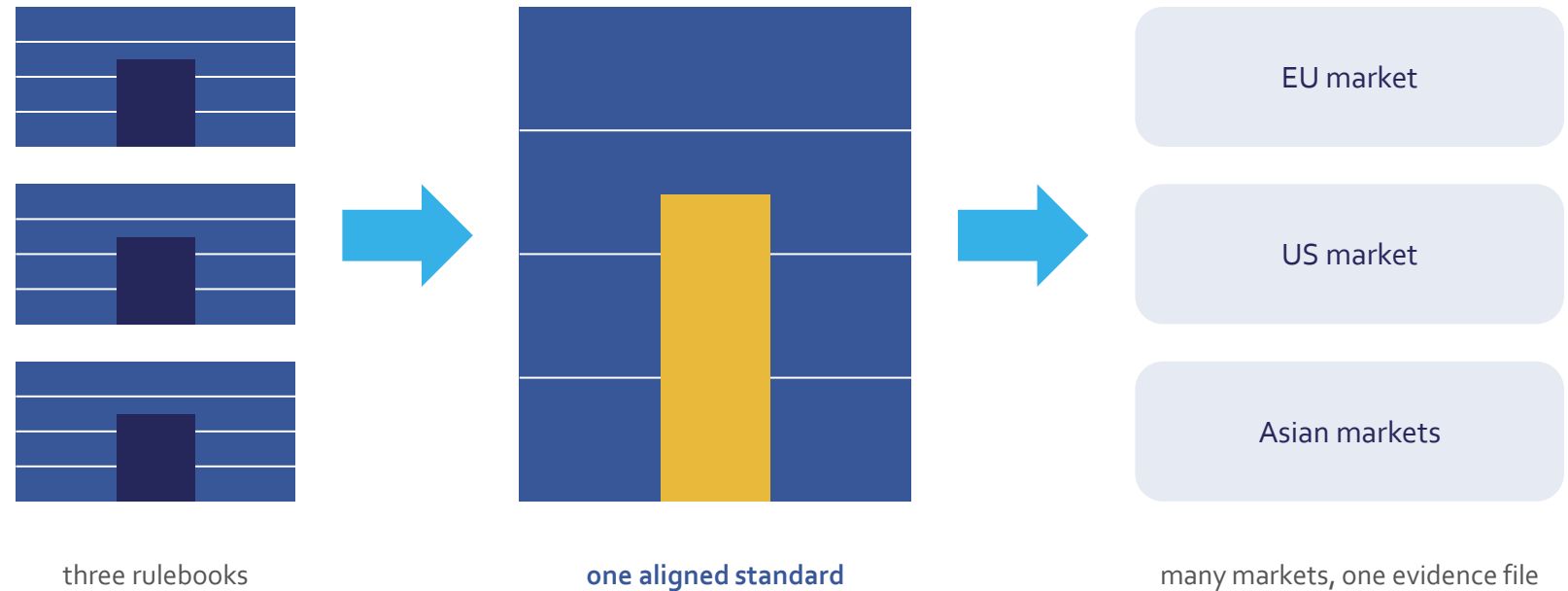
Manufacturers and sellers prepare before the border, in both directions.

Read the rulebook, map the product, build the evidence file, keep it current. The method does not change.

Our prospect: the EU compliance method and platform, applied to entry into other markets.

Standards are the door in every wall

Regulation divides markets. Aligned standards reconnect them. That alignment is the next challenge.



A regulation says what must be true. A standard says how to prove it. Only the second crosses a border. Fragmentation multiplies compliance cost by the number of markets. Big companies absorb it, SMEs pay it in full. Alignment is SME policy.

Once compliance is data, alignment is a mapping problem: comply once, render many. Multi-country R&D consortia are where that alignment starts.



[CelticNextEurekaCluster](https://www.linkedin.com/company/CelticNextEurekaCluster)



[@CelticNext](https://twitter.com/@CelticNext)



[CELTIC-NEXT Video Channel](https://www.youtube.com/channel/CELTIC-NEXT)

MANY THANKS FOR YOUR ATTENTION.

CELTIC-NEXT



- Thank you
- Taner Gülez
- taner@artechconsulting.net
- www.artechconsulting.net