EUROPEAN REGULATORY GATE

Gate Decision Report

Version 1 | Issued 2026-09-22 | Report sample-aura-sense-glow-patch

ILLUSTRATIVE SAMPLE

This report uses a fictional product and illustrative cost and timing ranges. It is not legal advice, a formal classification or a supplier quotation.

AuraSense Glow Patch v1.0 (fictional product)

Target: Germany, France, Netherlands | Channels: Direct-to-consumer e-commerce

1 Decision snapshot

The short commercial reading of the regulatory position, cost range and launch exposure.

VERDICT	COMPLEXITY
PROCEED	HIGH

ENTRY BUDGET	TIME TO MARKET
7,400-13,600 EUR	30-55 days

RECURRING COST	CLASSIFICATION CONFIDENCE
1,200-1,800 EUR / year	EXPERT DETERMINATION REQUIRED

Executive interpretation

The product currently maps to 4 likely regulatory routes. The overall verdict is PROCEED and the assessed complexity is HIGH. The estimate excludes 1 unresolved cost exposure, so it should be treated as a decision range rather than a supplier quotation. The most important open question is: Formal MDR classification determination for the light-therapy claim.

Decision-critical unresolved issue

Formal MDR classification determination for the light-therapy claim.

CRITICAL ISSUES TO CLOSE

- Medical-type claim may trigger MDR Class IIa

2 Assessment scope

What was assessed and which assumptions define the boundary of this decision.

PRODUCT VERSION

AuraSense Glow Patch v1.0

CLAIMS AND INTENDED USE REVIEWED

Bluetooth-connected wearable LED patch marketed for improving skin appearance. The draft product copy also uses 'light therapy' language. Companion app records session history and controls the device. No AI functionality is included.

MATERIAL ASSUMPTIONS

- Non-EU manufacturer selling directly to EU consumers.
- Bluetooth 5.2 module is pre-certified, but integration testing is still required.
- The patch is non-invasive and does not measure or diagnose a condition.
- No children's use, sterile presentation, medicinal substance or AI functionality.
- Budget excludes VAT, product redesign, translation and any Notified Body fees triggered by a medical-device classification.

Why assumptions matter

The recommendation is only valid while these assumptions remain true. A change in claims, product architecture, market channel or economic-operator setup can change the applicable route, cost and schedule.

3 Regulatory route

Each route below explains why it may apply, the evidence supporting it and what still needs to be resolved.

Radio Equipment Directive 2014/53/EU (RED)

PRIMARY | HIGH

Any intentional radio transmitter brings the finished product within RED scope regardless of its primary consumer function.

WHAT SUPPORTS THIS ROUTE

The product intentionally transmits data over Bluetooth.

WHAT POINTS AWAY FROM IT

None identified from the supplied product description.

WHAT STILL NEEDS AN ANSWER

Final antenna layout and module integration evidence.

Cyber Resilience Act (EU) 2024/2847 (CRA)

PRIMARY | HIGH

The connected device and companion software require cybersecurity risk assessment, documentation and vulnerability handling.

WHAT SUPPORTS THIS ROUTE

The device, mobile app and cloud connection form a connected product with digital elements.

WHAT POINTS AWAY FROM IT

None identified.

WHAT STILL NEEDS AN ANSWER

Support period, vulnerability handling process and software bill of materials.

Medical Devices Regulation (EU) 2017/745 (MDR)

PENDING DETERMINATION | EXPERT DETERMINATION REQUIRED

A formal claim and intended-purpose review is required before MDR can be excluded or a device class confirmed.

WHAT SUPPORTS THIS ROUTE

The phrase 'light therapy' may communicate a medical intended purpose.

WHAT POINTS AWAY FROM IT

The core description is cosmetic and makes no explicit disease claim.

WHAT STILL NEEDS AN ANSWER

Final intended purpose, packaging, website claims and instructions for use.

General Product Safety Regulation (EU) 2023/988 (GPSR)

PRIMARY | MEDIUM

GPSR obligations remain relevant for residual consumer-safety, traceability and distance-sale information.

WHAT SUPPORTS THIS ROUTE

The product is offered directly to EU consumers online.

WHAT POINTS AWAY FROM IT

Sector-specific legislation may cover some hazards.

WHAT STILL NEEDS AN ANSWER

Final economic-operator setup and online listing content.

EU Artificial Intelligence Act (EU) 2024/1689

EXCLUDED | HIGH

The current product description contains no AI system functionality.

WHAT SUPPORTS THIS ROUTE

No model-based inference, recommendation or automated decision function is described.

WHAT POINTS AWAY FROM IT

None.

WHAT STILL NEEDS AN ANSWER

Reassess if AI functionality is added to the app.

4 Requirements and actions

The practical work packages that convert the identified route into launch-ready evidence.

Complete RF, EMC and electrical-safety testing for the finished Bluetooth product.

HIGH IMPACT

Current position: Evidence not supplied.

LEGAL BASIS
Directive 2014/53/EU, Article 3

WHY IT APPLIES
Applicable to the final radio-equipment configuration.

WHAT TO DO NEXT
Book an accredited laboratory after hardware and antenna layout are frozen.

Prepare a RED Technical Construction File and EU Declaration of Conformity.

HIGH IMPACT

Current position: Not started.

LEGAL BASIS
Directive 2014/53/EU, Articles 10 and 17

WHY IT APPLIES
Applicable before placing the product on the EU market.

WHAT TO DO NEXT
Compile design, risk, test, labeling and production-control evidence.

Document cybersecurity risks across the device, app and cloud data flow.

HIGH IMPACT

Current position: Not started.

LEGAL BASIS
Regulation (EU) 2024/2847, Article 13

WHY IT APPLIES
Applicable to the connected product with digital elements.

WHAT TO DO NEXT
Define the support period, vulnerability process, update policy and security evidence.

Freeze the intended purpose and remove or substantiate medical-type claims.

CRITICAL IMPACT

Current position: Open classification issue.

LEGAL BASIS

Regulation (EU) 2017/745, Articles 2 and 7

WHY IT APPLIES

Required to determine whether MDR applies.

WHAT TO DO NEXT

Run formal claim and classification review before final packaging approval.

Align product, packaging and online listing traceability information.

MEDIUM IMPACT

Current position: Not evidenced.

LEGAL BASIS

Regulation (EU) 2023/988, Articles 9, 16 and 19

WHY IT APPLIES

Applicable to EU consumer sales and distance offers.

WHAT TO DO NEXT

Confirm economic operator, contact details, identifiers, warnings and listing information.

5 Regulatory entry budget

An indicative planning range for entering the market, separated from known recurring obligations and unpriced exposure.

Current connected consumer-product design

PLANNING RANGE

One-off entry work is estimated at 7,400-13,600 EUR. Recurring compliance is estimated at 1,200-1,800 EUR per year.

COMMERCIAL INTERPRETATION

Use the low end for an evidence-ready product with stable scope and available suppliers. Use the high end where documentation gaps, testing iterations or specialist review are more likely.

EXCLUDED OR UNPRICED EXPOSURE

The following items require a separate quotation or determination: Notified Body If Mdr.

UNPRICED EXPOSURE DETAILS

- Notified Body conformity assessment if MDR Class IIa is confirmed (QUOTE REQUIRED)

6 Timeline and critical path

The likely duration if work starts with the present scope and no unresolved item expands the route.

Expected launch-readiness window

The current critical path is 30-55 days. The lower bound assumes prompt decisions and supplier availability; the upper bound includes the longer scheduling and evidence path currently identified.

FAST-PATH CRITICAL TASKS
Classification -> Lab Testing -> Technical File

CONSERVATIVE CRITICAL TASKS
Classification -> Lab Scheduling -> Lab Testing -> Technical File

Schedule exposure

No reliable duration is yet available for: Notified Body If Mdr. Do not make an external launch commitment until these items are priced and scheduled.

7 Regulatory risks

The situations most likely to change the cost, route or launch date, with a named mitigation and accountable owner.

Medical-type claim may trigger MDR Class IIa

CRITICAL

This risk becomes active when: Final marketing or instructions communicate treatment of a medical condition.

BUSINESS CONSEQUENCE
Notified Body assessment, additional clinical and technical evidence, and an estimated 3-6 month delay.

MITIGATION
Complete a formal intended-purpose and classification review before claims and packaging are frozen.

OWNER
Founder / regulatory lead

Bluetooth module evidence may not cover the finished product

HIGH

This risk becomes active when: Antenna, enclosure, power or coexistence changes invalidate module-level evidence.

BUSINESS CONSEQUENCE
Additional RF/EMC testing, redesign and delayed technical-file completion.

MITIGATION
Run a lab gap review on the frozen production configuration before booking the full campaign.

OWNER
Hardware lead

Cybersecurity support process is not defined

HIGH

This risk becomes active when: No documented support period, vulnerability intake or security update process.

BUSINESS CONSEQUENCE
CRA documentation gap and recurring post-market obligations not budgeted operationally.

MITIGATION
Assign product-security ownership and document vulnerability handling before launch.

OWNER
Software lead

9 Decision points

Management choices that should be made before more money is committed or the launch promise is fixed.

- Confirm whether 'light therapy' is commercially essential before freezing claims.
- Freeze the Bluetooth module, antenna and enclosure before final laboratory booking.
- Decide whether the recurring cybersecurity support obligation fits the product margin.

10 Recommendation and verdict

The recommended commercial posture based on the frozen assessment scope.

Verdict: PROCEED

Proceed to formal claim classification and RED/CRA evidence planning. Do not commit to final packaging or a launch date until the MDR question is resolved. The current REB is commercially plausible for a connected consumer product, but excludes any Notified Body route that may be triggered by the final medical-type claim.

11 Sources and limitations

How to read the report responsibly and where its conclusions stop.

Illustrative Gate Decision sample for a fictional product. The assessment is indicative, depends on the stated assumptions and must not be used as a legal opinion, conformity decision or substitute for formal classification.

ASSESSMENT ISSUE DATE
2026-09-22

FROZEN SCOPE VERSION
1

MATERIAL LIMITATIONS

- All product, market and evidence details in this report are fictional.
- Cost and timeline ranges are illustrative and not supplier quotations.
- The report does not constitute legal advice or formal regulatory classification.

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12 Recommended next steps

A practical sequence for turning this decision into controlled execution.

- Close the decision-critical issue first: Formal MDR classification determination for the light-therapy claim.
- Convert the 5 identified requirements into an owner-and-deadline action plan.
- Request written supplier quotations for every unpriced exposure before approving the final launch budget.
- Resolve unknown-duration tasks before announcing a fixed launch date.
- Re-run the Gate Decision whenever claims, design, software functions, target markets or sales channels materially change.

Use external providers selectively

These links help find relevant specialists and representative services. Inclusion is not an endorsement, and the final scope, qualifications, price and availability must be verified directly with the provider.

MOST RELEVANT FOR THIS CASE

European Compliance Platform (ECP)
Find and compare EU compliance providers, including testing laboratories, certification bodies, Notified Bodies, authorised representatives and regulatory consultants.
https://eucertify.com/

getCE.eu
CE-marking route support: applicable legislation, technical documentation, risk assessment, test coordination and Notified Body selection where required.
https://getce.eu/

getMDR.eu
MDR and IVDR strategy, technical-documentation readiness, clinical or performance evidence planning and Notified Body coordination.
https://getmdr.eu/

getEAR.eu
EU Authorised Representative and PRRC services for non-EU medical-device and IVD manufacturers under MDR and IVDR.
https://getear.eu/

getGPSR.eu
EU Responsible Person support under GPSR Article 16 for non-CE consumer products sold by non-EU manufacturers and sellers.
https://getgpsr.eu/

representAI.eu
Article 22 AI Act Authorised Representative services for non-EU providers of high-risk AI systems.
https://representai.eu/

OTHER SPECIALIST EU SERVICES

getCosmeticRP.eu
EU Cosmetics Responsible Person services, including PIF custody, CPSR coordination, CPNP notification and market-surveillance cooperation.
https://getcosmeticrp.eu/

getREACHOR.eu
REACH Only Representative services for non-EU substance manufacturers, including REACH-IT registration, records and authority cooperation.
https://getreachor.eu/