

Automate Everything

How to raise the bar on compliance



- Strong collaboration
- Version everything in a single timeline for traceability
- Continuously run all automation with every change

Strong Collaboration

What?

Who does that raise the bar on compliance?

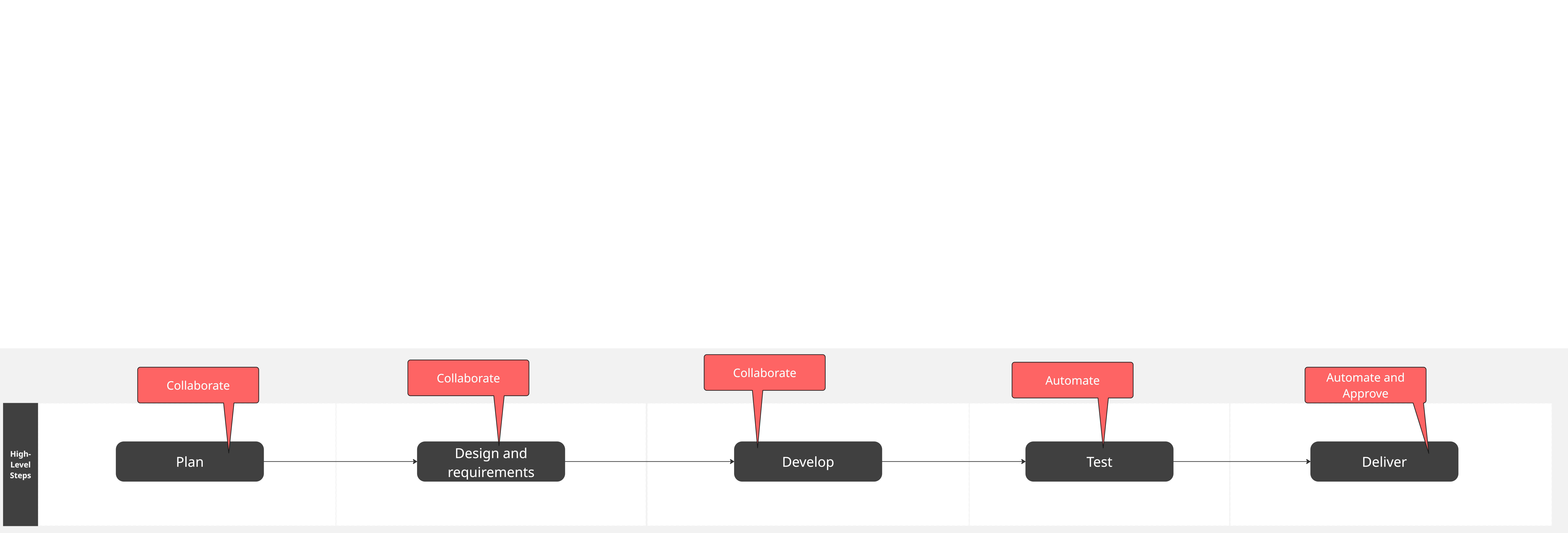
Specifications

Shared language

Shared mental model
Domain Driven Design

Slicing

Value Stream Mapping



Traceability

How does automation guarantee traceability?

Structure and Tagging

@critical @gxp @data-integrity

Feature: Patient Data Integrity

As a clinical data manager

I want to ensure patient data integrity is maintained

So that clinical trial data remains compliant with GxP regulations

@req:URS-001 @audit-trail

Rule: All patient data modifications must create audit trails

@critical

Scenario: Patient data modification creates audit trail



Given a patient record exists in the system

When the patient's weight is updated from "70kg" to "72kg"

Then an audit trail entry is created

And the audit trail contains the original value "70kg"

And the audit trail contains the new value "72kg"

And the audit trail contains the user who made the change

And the audit trail contains the timestamp of the change

@critical

Scenario: Multiple field updates create separate audit entries

Given a patient record exists in the system

When the patient's height is updated from "170cm" to "175cm"

And the patient's weight is updated from "70kg" to "72kg"

Executable Specifications

@critical @gxp @data-integrity

Feature: Patient Data Integrity

As a clinical data manager

I want to ensure patient data integrity is maintained

So that clinical trial data remains compliant with GxP regulations

@req:URS-001 @audit-trail

Rule: All patient data modifications must create audit trails

@critical

Scenario: Patient data modification creates audit trail

- ✓ **Given** a patient record exists in the system
- ✓ **When** the patient's weight is updated from "70kg" to "72kg"
- ✓ **Then** an audit trail entry is created
- ✓ **And** the audit trail contains the original value "70kg"
- ✓ **And** the audit trail contains the new value "72kg"
- ✓ **And** the audit trail contains the user who made the change
- ✓ **And** the audit trail contains the timestamp of the change

@critical

Scenario: Multiple field updates create separate audit entries

- ✓ **Given** a patient record exists in the system
- ✓ **When** the patient's height is updated from "170cm" to "175cm"
- ✓ **And** the patient's weight is updated from "70kg" to "72kg"
- ✓ **Then** two separate audit trail entries are created
- ✓ **And** each entry tracks its specific field change

@req:URS-002 @validation

Rule: Patient vital signs must be validated against clinical ranges

@critical

Version Control Systems

Or Source Code Management - git

GIT

- GitHub
- GitLab
- Azure DevOps Git
- Bitbucket
- and many others

Oct 17, 2025

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[feat] Add WIP specification for patient data integrity

Tomas Malmsten authored 6 minutes ago

cd0970d8

📄

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- 

[infra] Add emacs temp files to .gitignore

Tomas Malmsten authored 8 minutes ago

caefee51

📄

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[infra] Set up app build tooling using Gradle

Tomas Malmsten authored 40 minutes ago

b84abbe9

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▾	app/src/test/resources/features/patient_data_integrity.feature		+1	-1	☐ Viewed	💬	⋮
1	- @WIP @critical @gxp @data-integrity	1	+	@critical @gxp @data-integrity			
2	Feature: Patient Data Integrity	2		Feature: Patient Data Integrity			
3	As a clinical data manager	3		As a clinical data manager			
4	I want to ensure patient data integrity is maintained	4		I want to ensure patient data integrity is maintained			
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Continuous Delivery

What is CD?

What does it have to do with raising the bar of compliance?

“Our highest priority is to satisfy the customer through early and
Continuous delivery
of valuable software”

–Agile Manifesto Principles

Automate Everything

Building, testing, documentation, infrastructure, releasing, ...

Run it on every single change

**Every single change is a
potential release**

**So, let us make every change a
compliant possible release!**

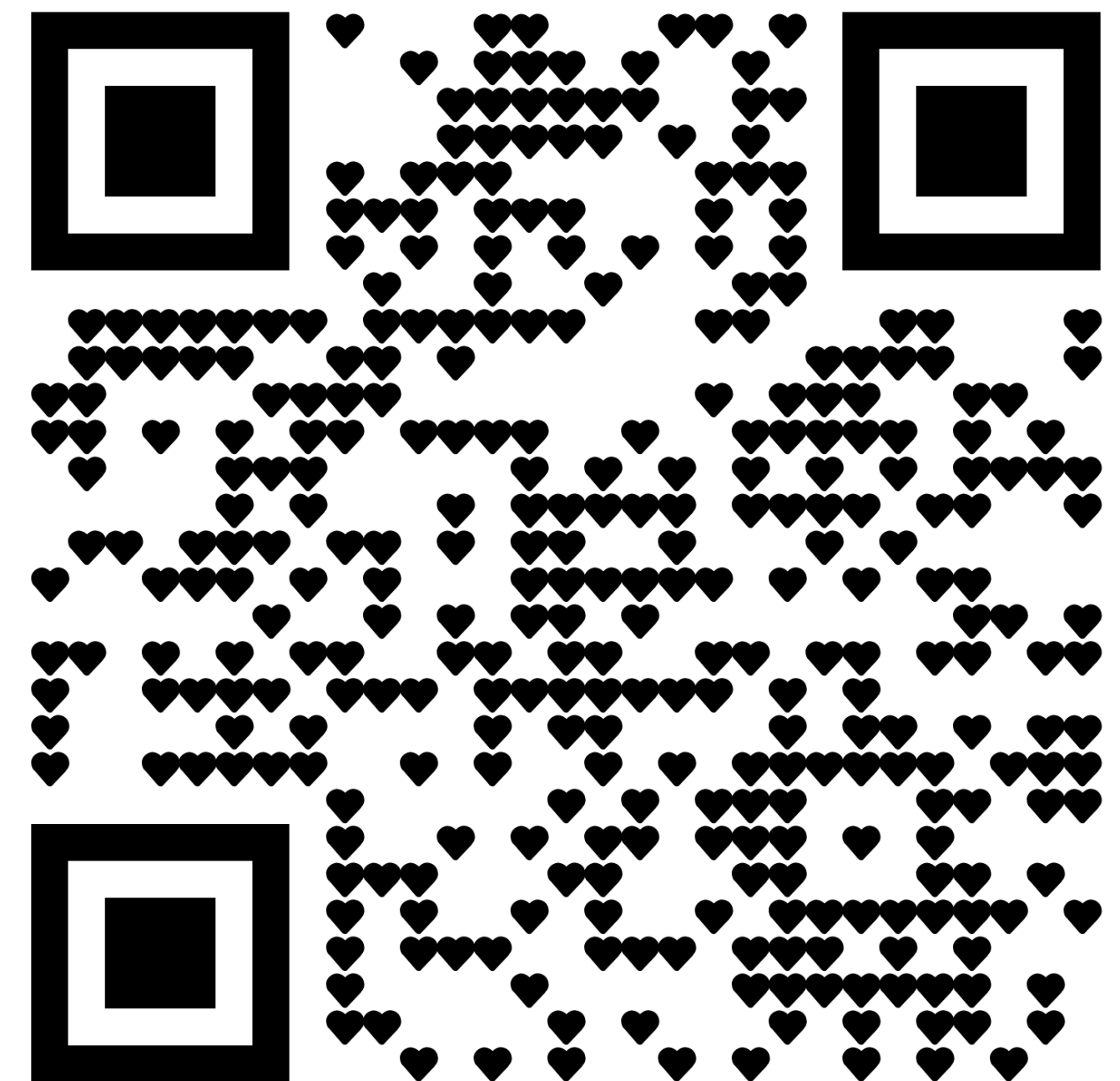
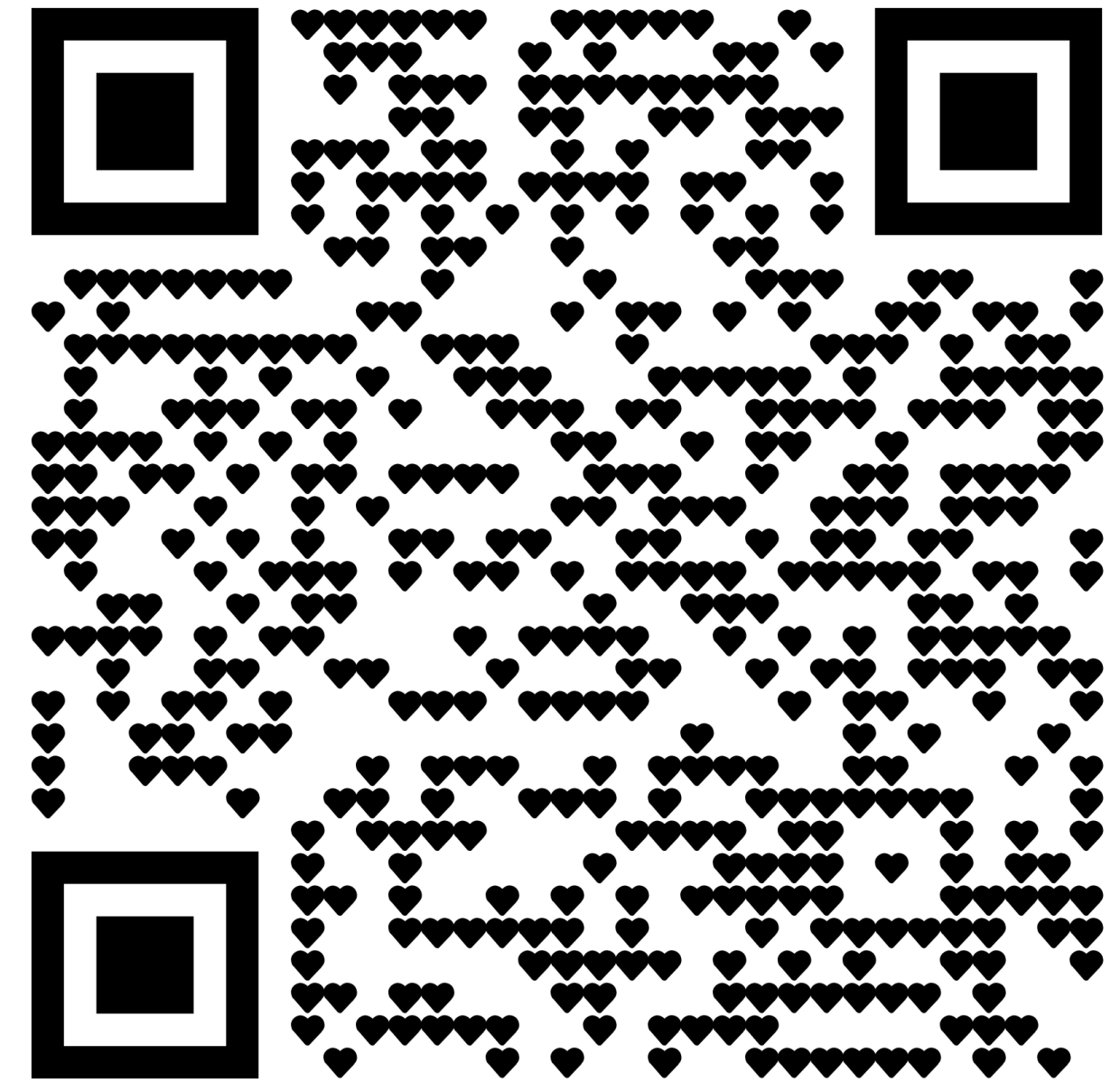
How to reach us

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Blog

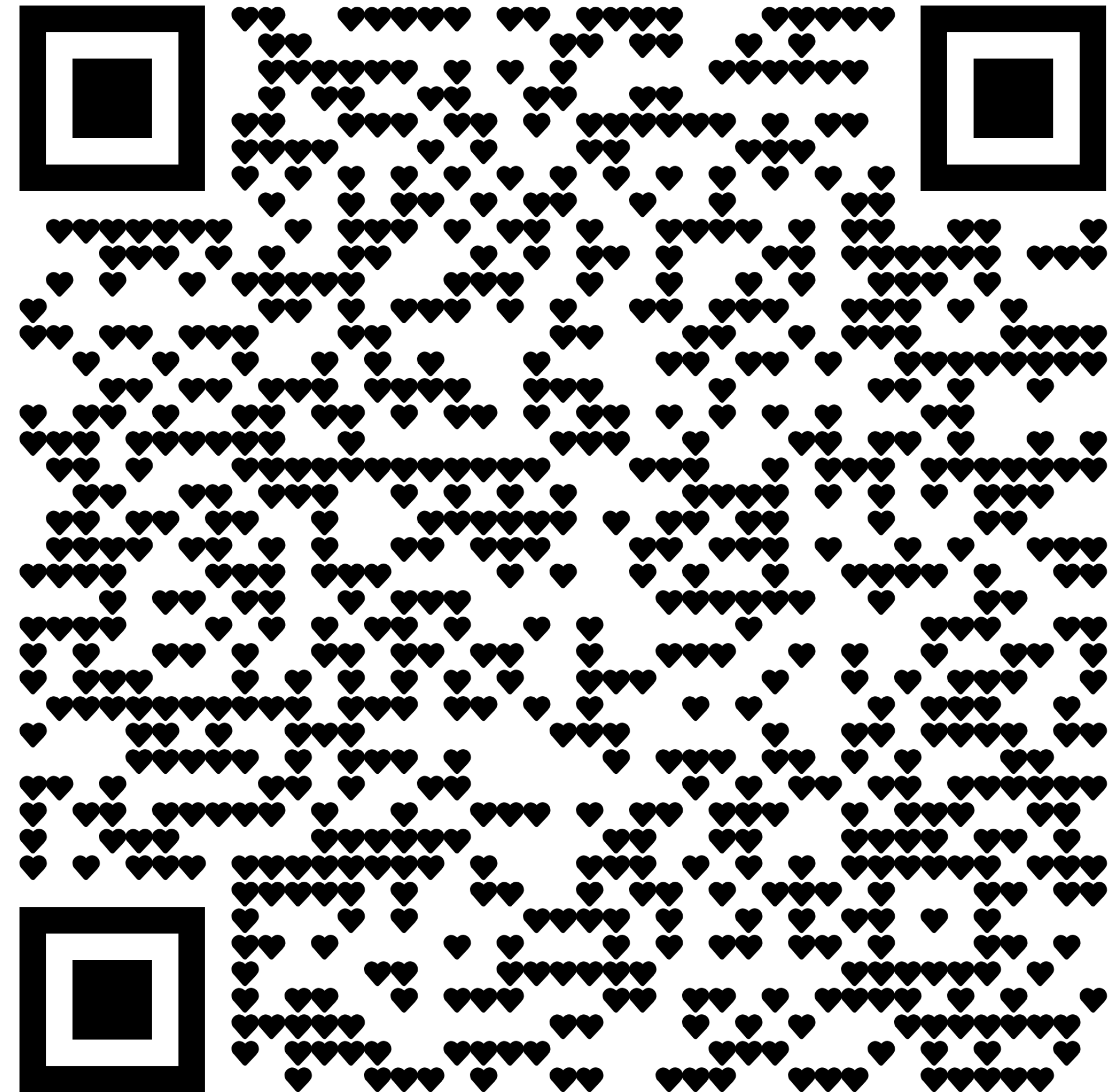
<http://tomasmalmsten.com/>



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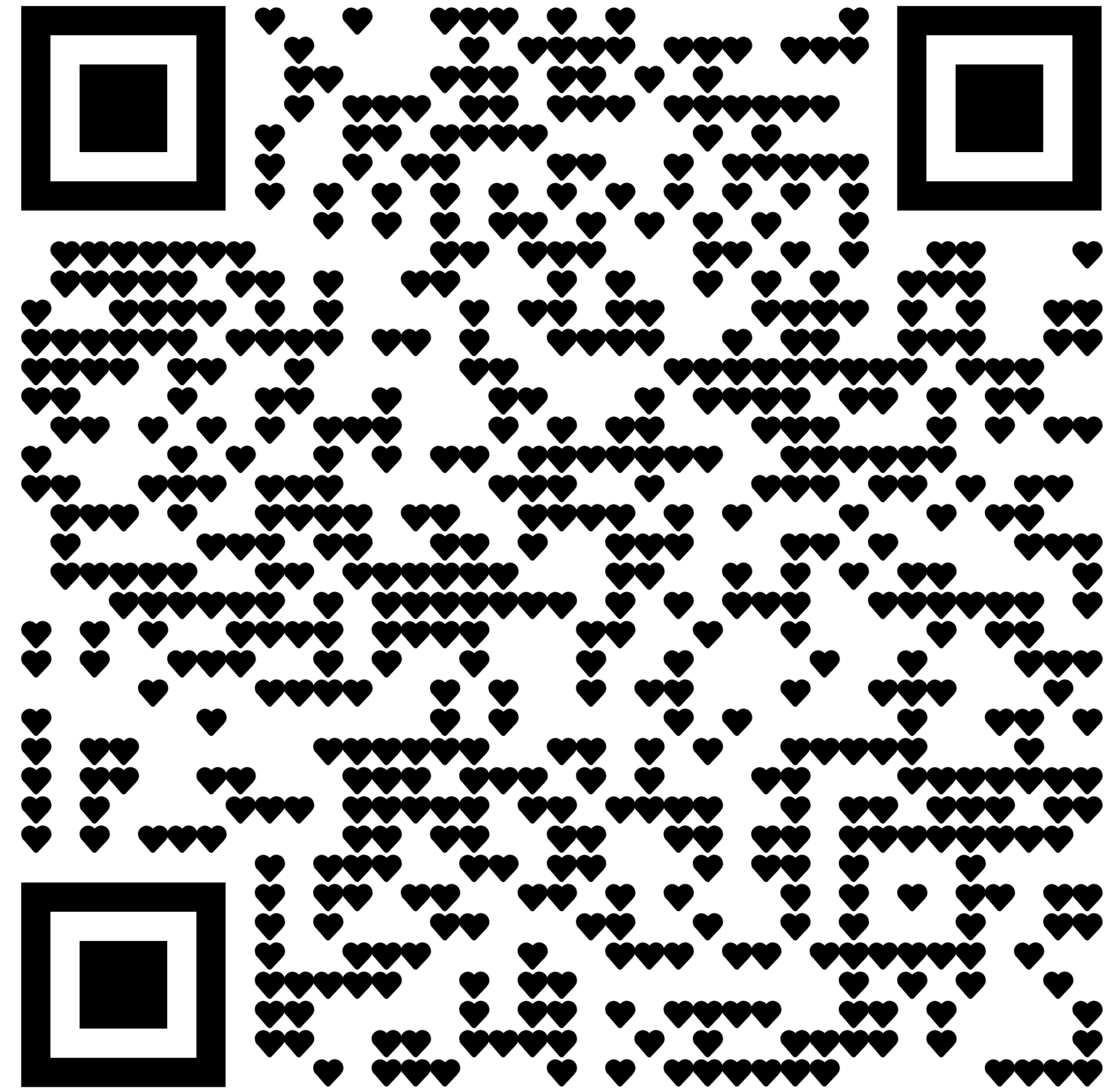
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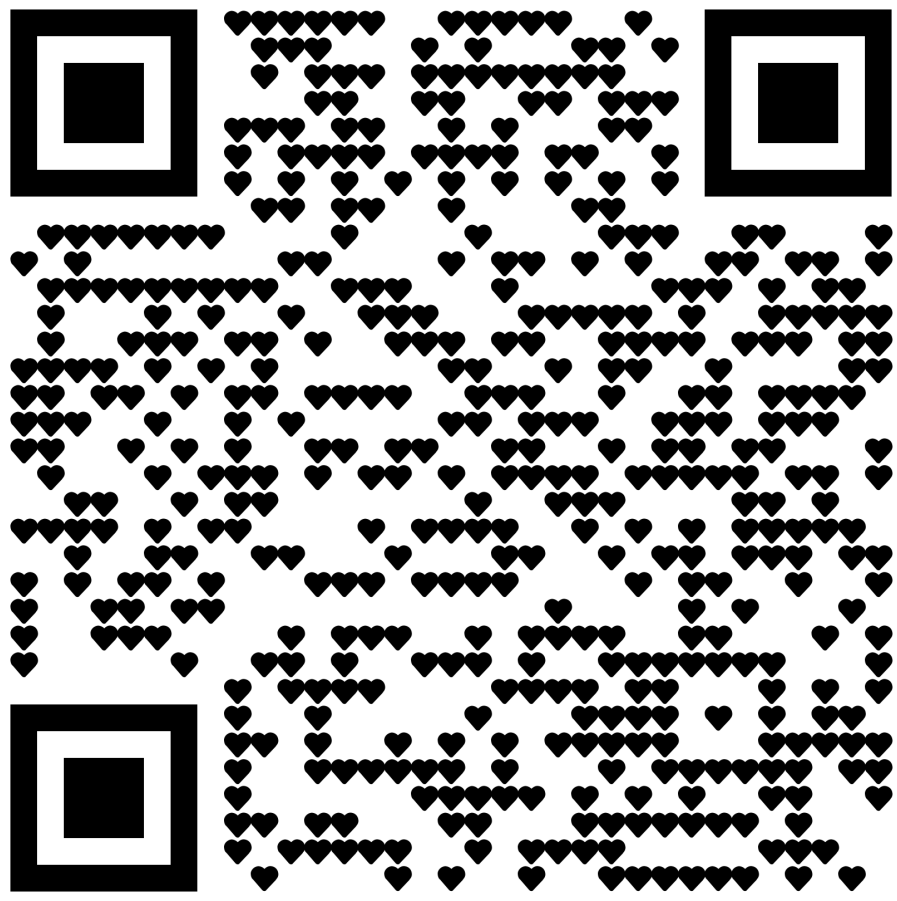


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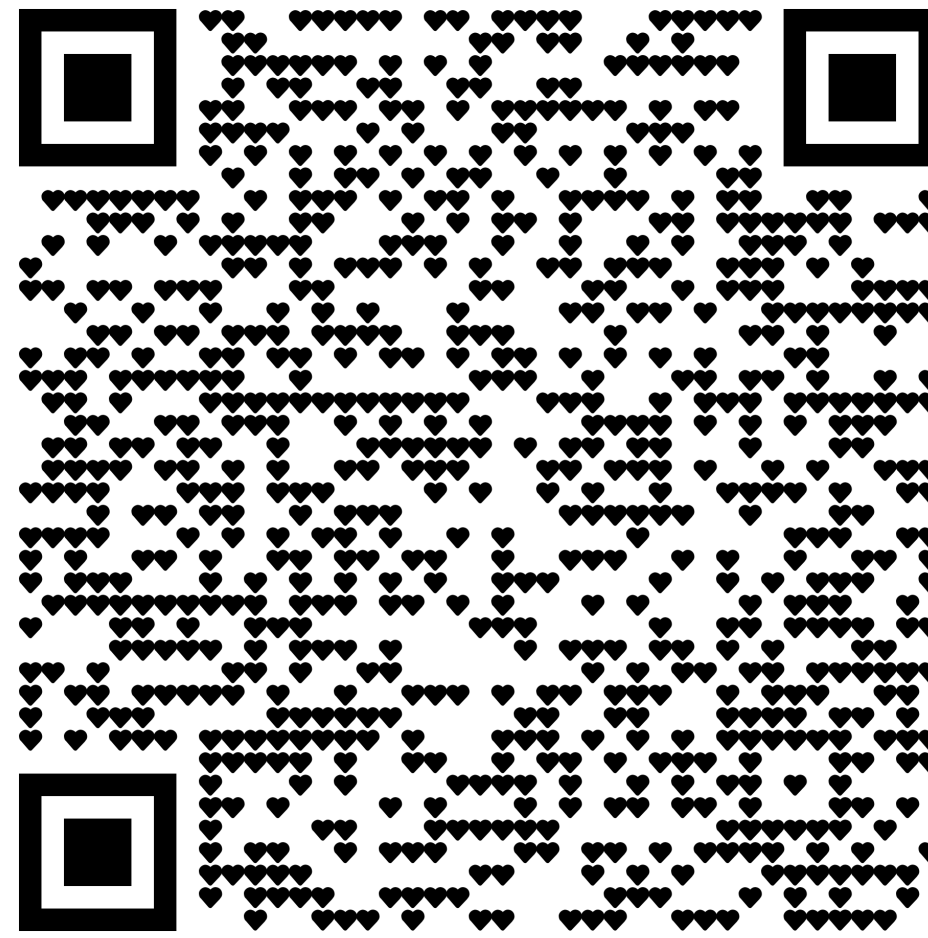
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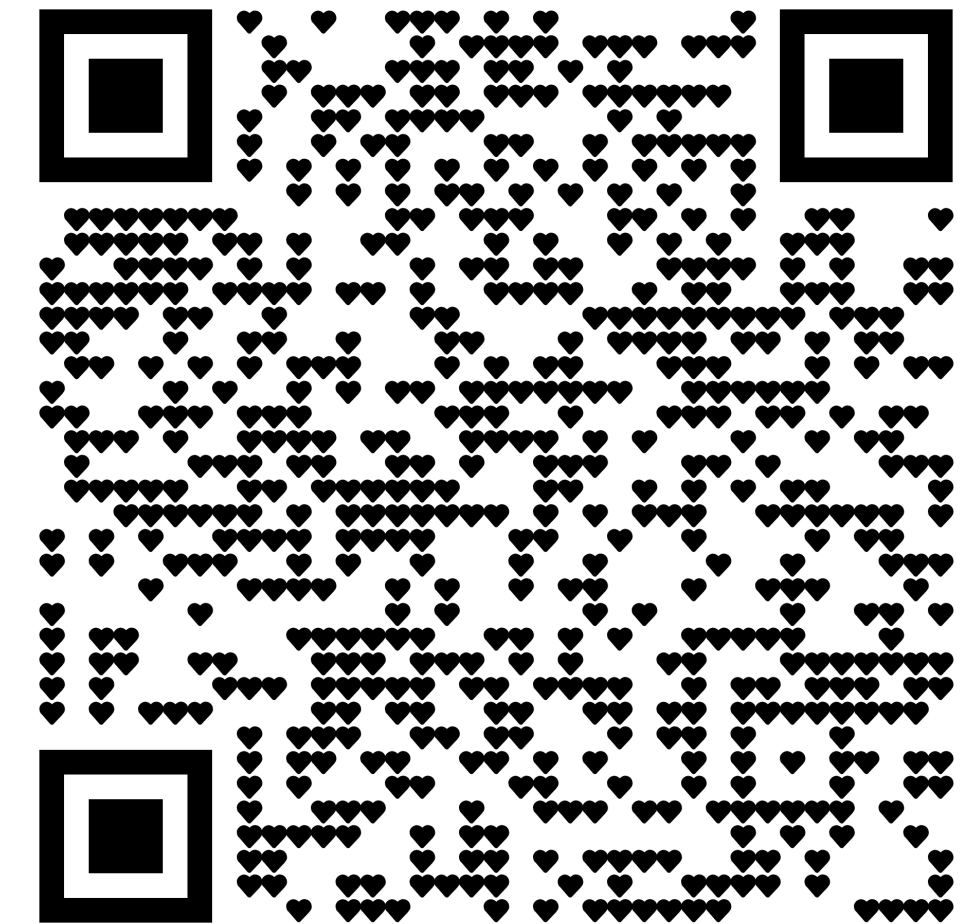




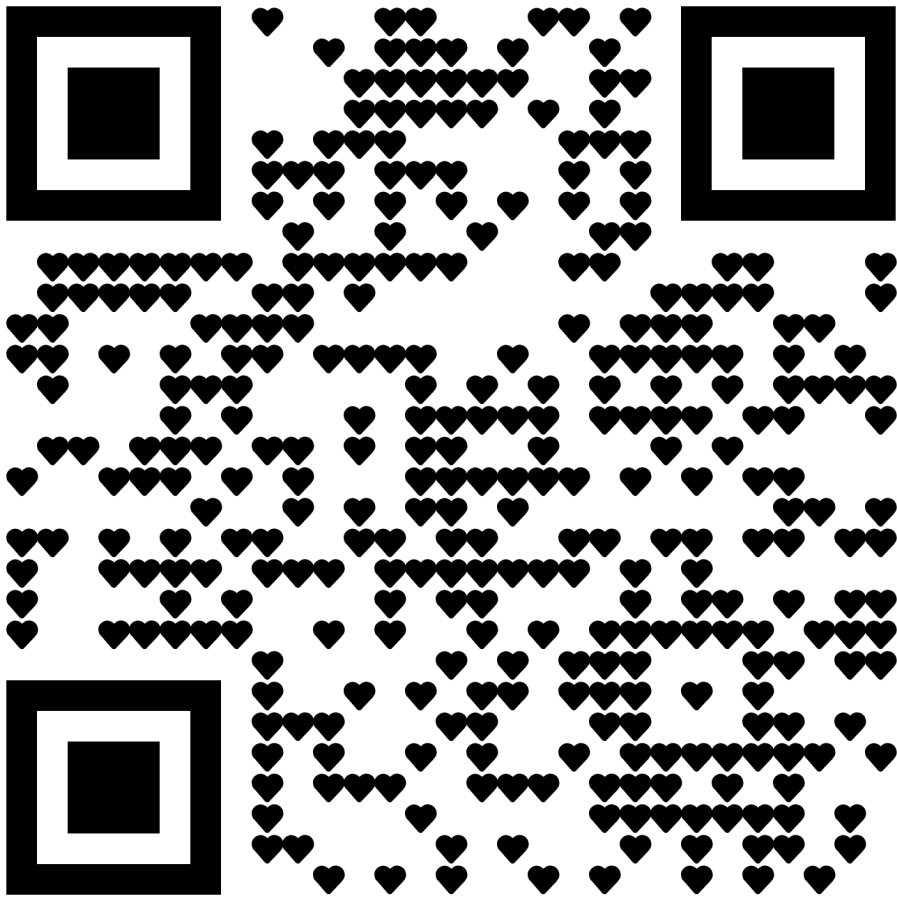
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