# EU Certificate

## for the assessment of the technical documentation

## according to Regulation on In-vitro Diagnostic Medical Devices (EU) 2017/746 Annex IX Chapter II

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the manufacturer

## DOASENSE GmbH

**Single Registration Number (SRN): DE-MF-000015367**
Waldhofer Straße 102, 69123 Heidelberg, Germany

that the technical documentation of the product(s) described in the annex complies with the provisions of the Regulation on In-Vitro Diagnostic Medical Devices (EU) 2017/746. The certificate is based on the results of the assessment of the technical documentation according to the Regulation on In-Vitro Diagnostic Medical Devices (EU) 2017/746 Annex IX Chapter II, which are recorded in the report referred to in the annex.

Product: DOAC Dipstick

EU Certificate no.: 51551-71-A0-00

Certificate valid from: 2025-02-21
Certificate valid to: 2030-02-20

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-100

Digitally signed by Andre Schmitz
Date: 2025-02-21 14:30:00+01:00

DEKRA Certification GmbH, Stuttgart, 2025-02-21
Notified Body ID number: 0124

# Annex to the EU Certificate no. 51551-71-A0-00

This certificate covers the following device:

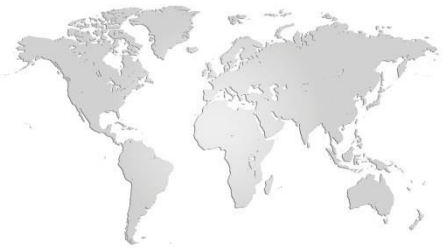
| **Class C, Near patient testing** | |
|---|---|
| **Basic UDI-DI:** 426055266DipstickH3<br><br>**Device Name:** DOAC Dipstick<br><br>**Model:** 0001<br><br>**Type:** W01010602 Clinical Chemistry; Rapid Test & Point of Care<br><br>**Conformity assessment procedure:** Annex IX, Chapter II Section 4, and 5.1, and Chapter III | Intended Purpose:<br><br>The diagnostic test strip DOAC Dipstick is intended for qualitative detection of the absence or presence of direct oral anticoagulants (DOACs: Dabigatran, Apixaban, Edoxaban, and Rivaroxaban) in human urine by visual identification of colours. The DOAC Dipstick is an in vitro diagnostic test and can be used at the Point of Care (POCT / Near Patient Test) or in the laboratory. The DOAC Dipstick is intended for professional use only. |

Change to previous certificate: n.a.

Remark: For the placing on the market of the product(s) referred to above, an additional EU certificate for the assessment of the quality management system in accordance with Annex IX Chapter I + III is required.

# EU Certificate

## for the assessment of the quality management system



## according to Regulation on In-vitro Diagnostic Medical Devices (EU) 2017/746 Annex IX Chapter I+III

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the manufacturer

## DOASENSE GmbH

**Single Registration Number (SRN): DE-MF-000015367**
Waldhofer Straße 102, 69123 Heidelberg, Germany

applies a quality management system according to Annex IX Chapter I+III of the regulation on in-vitro diagnostic medical devices (EU) 2017/746 for the devices listed in the annex. This certificate is based on the assessments listed in CNo51551-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 51551-70-00-00

Certificate valid from: 2025-02-21
Certificate valid to: 2028-04-04

Digitally signed by Andre Schmitz
Date: 2025-02-21
14:07:43+01:00

DEKRA Certification GmbH, Stuttgart, 2025-02-21
Notified Body ID: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-100

# Annex to the EU Certificate no. 51551-70-00-00

Following devices/device categories are included in this certificate:

Class C near-patient test devices

DOAC Dipstick

Intended Purpose:

The diagnostic test strip DOAC Dipstick is intended for qualitative detection of the absence or presence of direct oral anticoagulants (DOACs: Dabigatran, Apixaban, Edoxaban, and Rivaroxaban) in human urine by visual identification of colours. The DOAC Dipstick is an in vitro diagnostic test and can be used at the Point of Care (POCT / Near Patient Test) or in the laboratory. The DOAC Dipstick is intended for professional use only.

Basis-UDI-DI: 426055266DipstickH3

- Level 1: Class C for near-patient testing
- Level 2: IVR0605 Devices intended to be used for monitoring of levels of medicinal products, substances or biological components
- Level 3: W01010602 Clinical Chemistry; Rapid Test + Point-of-Care-Test
- Level 4: 426055266DipstickH3
- Level 5: IVP 3002 In vitro diagnostic devices which require knowledge regarding biochemistry

Change to previous certificate: n.a.