Number: 2305503TD01

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/746 on In Vitro Diagnostic devices, Annex IX Chapter II and III

Manufacturer:

DOASENSE GmbH

Waldhofer Strasse 102
69123 Heidelberg
Germany
SRN ID.: DE-MF-000015367

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2305503CN

Additional certificate: 2305503CE01

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/746, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/746. For placing these products on the market an Annex IX EU Quality Management System certificate is also required.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

F. Godeke
Principal Certification Manager

First Issued: **23 February 2026** Date: **23 February 2026** Expiry date**: 1 February 2030**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 2305503TD01

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/746 on In Vitro Diagnostic devices, Annex IX Chapter II and III

This certificate covers the following device(s):

Class C, Near patient testing	
Basic UDI-DI: 426055266DipstickH3 **Device Name:** DOAC Dipstick **Type:** W0101-Clinical Chemistry; Rapid Test & Point of Care **Model:** 0001	*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.*

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	23 February 2026	2305503CN02	First issue
1	2 March 2026	2305503CN02.1	Revised

First Issued: **23 February 2026** Date: **23 February 2026** Expiry date**: 1 February 2030**

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Number: 2305503CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/746 on In Vitro Diagnostic devices, Annex IX Chapter I and III

Manufacturer:

DOASENSE GmbH

Waldhofer Strasse 102
69123 Heidelberg
Germany
SRN ID.: DE-MF-000015367

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2305503CN

Additional certificate: 2305503TD01

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/746, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/746.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

F. Godeke
Principal Certification Manager

First Issued: **23 February 2026** Date: **23 February 2026** Expiry date**: 1 February 2030**

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T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 2305503CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/746 on In Vitro Diagnostic devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Clinical Chemistry (W0101, Class C) **In vitro diagnostic devices which require knowledge regarding biochemistry (IVP 3002)**	
Device Name: 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.*

Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

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