Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

No. V74 105329 0004 Rev. 00

Manufacturer:

iLine Microsystems S.L.
Paseo Mikeletegi 69
20009 Donostia (Gipuzkoa)
SPAIN

SRN Manufacturer - ES-MF-000013573

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, Section 4, 5.1 of this regulation with a positive result.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V74 105329 0004 Rev. 00

Report No.: 713317491_TD

Valid from: 2024-09-24
Valid until: 2029-09-23

Marta Carnielli
Head of Certification IVD

Issue date: 2024-09-24

Digitally signed by Latîşev Anastasia
Date: 2026.02.03 18:04:36 EET
Reason: MoldSign Signature
Location: Moldova
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No. V74 105329 0004 Rev. 00

Classification:	Class C
Device Group:	W0103020101 - PROTHROMBIN TIME (QUICK TEST)
Basic UDI-DI:	843654029microINRChipEU
Intended Purpose:	The microINR system is intended to monitor oral anti-coagulation treatment (OAT) with vitamin K antagonist drugs. The microINR system determines quantitative prothrombin time (PT) in INR (International Normalized Ratio) units with fresh capillary blood (performed by fingersticking). The microINR system is a medical device for in-vitro diagnostics intended for near-patient testing and self-testing use. The microINR Chips are intended to be used exclusively with the compatible microINR meters manufactured by iLine Microsystems.
Device(s):	microINR Chips Cat. No. CHB0025

Classification:	Class C
Device Group:	W0202020102 - AUTOMATED COAGULOMETERS
Basic UDI-DI:	843654029microINRKitSN
Intended Purpose:	The microINR system is intended to monitor oral anti-coagulation treatment (OAT) with vitamin K antagonist drugs. The microINR system determines quantitative prothrombin time (PT) in INR (International Normalized Ratio) units with fresh capillary blood (performed by fingersticking). The microINR system is a medical device for in-vitro diagnostics intended for near-patient testing and self-testing use. The microINR Chips are intended to be used exclusively with the compatible microINR meters manufactured by iLine Microsystems.
Device(s):	microINR Kit Cat. No. KTA0001 KTB0001

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No. V74 105329 0004 Rev. 00

Classification:	Class C
Device Group:	W0202020102 - AUTOMATED COAGULOMETERS
Basic UDI-DI:	843654029microINRLinkH5
Intended Purpose:	The microINR system is intended to monitor oral anti-coagulation treatment (OAT) with vitamin K antagonist drugs. The microINR system determines quantitative prothrombin time (PT) in INR (International Normalized Ratio) units with fresh capillary blood (performed by fingersticking). The microINR system is a medical device for in-vitro diagnostics intended for near-patient testing and self-testing use. The microINR Chips are intended to be used exclusively with the compatible microINR meters manufactured by iLine Microsystems.
Device(s):	microINR Link Kit Cat. No. KTD0001 KTE0001
-	
The validity of this certificate depends on conditions and/or is limited to the following:	For the meters which are part of the devices microINR Kit and microINR Link Kit listed above, the certificate covers the application for self-testing. For the microINR Chip the certificate covers the dual application for self-testing and near patient-testing.

Revision History:

Rev.	Dated	Report	Description
00	2024-09-24	713317491_TD	Initial issuance

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