

## QUALITY SYSTEM

# CERTIFICATE

# ISO 13485:2016

### **Oy Medix Biochemica Ab**

Klovinpellontie 1-3 FI-02180 Espoo Finland

Eurofins Electric & Electronics Finland Oy has assessed the company's quality system and found that it meets the requirements of ISO 13485:2016. This certificate covers the following functions/services:

The design and development, manufacture and sales of antibodies, antigens and other raw materials used in *in vitro* diagnostic devices and controls.

> Valid from: 17 December, 2024

Valid until: 3 November, 2026

First issued: 6 February, 2004

(before 4 July 2023, the certificate was issued by another certifying body)

Aliisa Siljander Decision Maker

Certificate nr. EUFI29-24001333-S





Tatja Purhonen

Lead Auditor

Certification body: Eurofins Electric & Electronics Finland Oy Kivimiehentie 4 FI-02150 ESPOO, FINLAND



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Annex to the Certificate EUFI29-24001333-S





	to the Certificate EOT 129-24001	555 5
Organisation	Oy Medix Biochemica Ab Klovinpellontie 1-3, FI-02180 Espoo, Finland	
The scope of the certification includes the following sites		
Head office: Oy Medix Biochemica Ab	Klovinpellontie 1-3, FI-02180 Espoo, Finland	
	The design and development, manufacture and sales of antibodies, antigens and other raw materials used in in vitro diagnostic devices and controls.	
Shanghai Medix Medical Technology Co., Ltd.	Floor 11, Building 6, No. 10 Lvzhou Ring Road., Minhang District, 201114 Shanghai, China	
	Administration, sales, product developmer	nt
Shanghai Medix Biochemica Co., Ltd.,	<ul> <li>Floor 11, Building 2, No. 10 Lvzhou Ring Rd., Minhang District, 201114 Shanghai, China</li> <li>Quality assurance, product development, production</li> </ul>	
	Valid from: 17 December 2024	
	Man Ju	0
	Aliisa Siljander	Tatja Purhonen
	Decision Maker	Lead Auditor

#### Medical Devices Kivimiehentie 4 FI-02151 Espoo - FINLAND

**EUROFINS ELECTRIC & ELECTRONICS FINLAND OY** 

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