

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2077826-1

Certificate Holder: W.H.P.M., Inc.
5358 Irwindale Avenue, Irwindale,
CA 91706
USA

Scope: Contracted Manufacture and Distribution of In-vitro Diagnostic Test Kits and In-vitro Diagnostic Reagents Used in the Diagnosis of Hormone Testing (incl. Follicle Stimulating Hormone, Luteinizing Hormone and human Choriongonadotropin Hormone), Drugs of Abuse Testing, Occult Blood Test (Hemoglobin and Transferrin Test) Incl. Home Use and Near Patient In-vitro Diagnostic Devices

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190169756-110

Effective date: 2025-09-23

Expiry date: 2028-09-22

Issue date: 2025-09-19

Replaces certificate SX 2077826-1 issued 2023-09-15

This certificate can be validated on <https://www.certipedia.com>



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