# CERTIFICATE OF ANALYSIS

This certificate is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid's Quality System, in compliance with the US Food and Drug Administration's Quality System Requirements, ISO 13485, European IVD Directive and the Canadian Medical Devices Regulations (CMDR).

**Product Name:** Xpert® MRSA

**Cepheid Catalogue Part No.:** GXMRSA-100N-10

**Kit Lot No.:** 1001452745

**Cartridge Lot No.:** 25306

**Kit Expiration Date:** 2026-09-27

**Legal Manufacturer**
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

**Manufacturing Facility**
Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

○ Solna ○ Sunnyvale

◉ Lodi

***Functional Testing according to D16895, Rev.*** AA

| *Test Description* | *Acceptance Criteria* | *Test Result* |
|---|---|---|
| Positive | MRSA Positive | Passed |
| Negative | MRSA Negative | Passed |

☐ If checked, this document is produced electronically and therefore valid without a wet signature

MW 25OCT24

**Signature of Quality Assurance,** **Date**

**Name:** Meiling Wu

**Title:** Quality Assurance Specialist