

## **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.: 1000769510

Cartridge Lot No.: 23901

Kit Expiration Date: 2025-02-09

Legal Manufacturer

Manufacturing Facility

Cepheid

Cepheid

Solna

Sunnyvale

904 Caribbean Drive Sunnyvale, CA 94089 USA 904 Caribbean Drive Sunnyvale, CA 94089

**USA** 

Lodi

## Functional Testing according to D16895, Rev. Y

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

Signature of Quality Assurance,

03/11/2023

Name: ThuyTien Nguyen

Title:

Quality Systems Specialist