

## **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.: 1001026164
Cartridge Lot No.: 23919
Kit Explication Data: 2025 06 15

Legal Manufacturer	<b>Manufacturing Facility</b>	-	
Cepheid	Cepheid	Solna	Sunnyvale
904 Caribbean Drive	121 N Guild Avenue	G Boilin	Sumyvano
Sunnyvale, CA 94089 USA	Lodi, CA 95240		
	USA	<ul><li>Lodi</li></ul>	

## 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

Signature of Quality Assurance,

Date

Name: Crystal Sysenglath

Title: Quality Systems Specialist