

Title: Quality Systems Specialist

## **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 Device Regulations (CMDR).

Directive and the Canadian Medical Device Regulations (CMDR).		
Product Name: Xpert® MRSA		
Cepheid Catalogue Part No.: GXMRSA-100N-10		
Kit Lot No.: 1000711660		
Cartridge Lot No.: 23810		
Kit Expiration Date: 2025-01-19		
Legal Manufacturer	Manufacturing Facility O Solna © S	Sunnyvale
Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	
Functional Testing		
Test Description	Acceptance Criteria	Test Result
Positive	MRSA Positive	Passed
Negative	MRSA Negative	Passed
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An'	02/06/23	
Signature of Quality Assurance Date		
Name: Rhoziel Cusi		