

Name: Austin Mei

Title: Quality System 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 Frederic Period Regulations (CIVIDIC).			
Product Name: Xpert	® MRSA		
Cepheid Catalogue Part No.: GXMRSA-100N-10			
Kit Lot No.: 1000	689516		
Cartridge Lot No.: 23808			
Kit Expiration Date: 2025-01-05			
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 U	JSA	Manufacturing Facility O Solna Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	Sunnyvale
Functional Testing			·
Test Description	Acceptance Criteria		Test Result
Positive	MRSA Positive		Passed
Negative	MRSA Negative		Passed
Ausfinger 01/29/23			
Signature of Quality Assurance Date			