



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/SA SSTI

Catalogue Part No.: GXMRSA/SA-SSTI-CE

Kit Lot No.: 1001447002

Cartridge Lot No.: 16401

Kit Expiration Date:2026-06-07

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden


Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Functional Testing

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	MRSA Positive/SA Positive	Passed
Negative	MRSA Negative/SA Negative	Passed

If checked this document is produced electronically and valid without a wet signature.

 2024-09-24
Signature of Quality Assurance Date

Name: Alexander Avramidis

Title: QA Analyst