

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.: GXMF	RSA-100N-10				
Kit Lot No.: 1001112805					
Cartridge Lot No.: 23924					
Kit Expiration Date: 2025-07-27					
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	Manufacturing Facility Cepheid 121 N Guild Avenue Lodi, CA 95240 USA	○○	Solna Lodi	0	Sunnyvale
Functional Testing according to D.	16895, Rev.				
	Acceptance Criteria		Test Result		
Test Description	Acceptance Criteria		ACDI ALI	20444	
Positive Positive	MRSA Positive		Pass		1
	<u>-</u>			ed	
Positive Negative	MRSA Positive MRSA Negative deed electronically and therefore valid w	vithout a	Pass	ed ed	
Positive Negative	MRSA Positive MRSA Negative	vithout a	Pass	ed ed	
Positive Negative If checked, this document is produ	MRSA Positive MRSA Negative Iced electronically and therefore valid was a second control of the second contr	vithout a	Pass	ed ed	