

Blood Cell Storage, Inc. 4203 23rd Ave W. Seattle WA, 98199 USA

Certificate of Compliance

Date of Manufacture: 07 July 2022

Product Name: BCSI pH SAFE Reader (pH1000TM)

Part Number: 400001

Lot Number: 2207001[†]

BCSI pH1000 Serial Number: BCS0804P0097

BCSI pH1000 QC Standard Serial Number: B398

Serial Number	Fr	Fp	Rp
B398	1349	2366	1.740



B3981349236617400183

NOTE: These criteria are specific for the pH1000 paired with the QC Standard as stated above. The Fr and Fp values must be within 5% of the listed value. The Rp value must be within 1% of the listed value.

USER: _____ EXPIRY[†]: _____ One (1) year from date of barcode scan

USER: Record the expiry date on the SQC label.

BCSI certifies that the above referenced product:

- Was tested by BCSI whose Quality Management System is approve by an accredited registering body to the appropriate ISO 13485:2016 Medical Devices Quality Systems Standard and ISO 9001:2015 Quality Systems Standard.
- Was tested in accordance with applicable BCSI Standard Procedures.
- Was tested and complies with visual and performance specifications as specified in the product specification.

一個性質	Quality
	ISO 13485 ISO 9001
DEKRA Cortified	www.dekra-seal.com

Steve Geelhood Business Director 0 / 541 0

Date

400001-07



Blood Cell Storage, Inc. 4203 23rd Ave W. Seattle WA, 98199 USA

Certificate of Compliance

Date of Manufacture: 07 July 2022

Product Name: BCSI pH SAFE Reader (pH1000TM)

Part Number: 400001

Lot Number: 2207001[†]

BCSI pH1000 Serial Number: BCS0804P0102

BCSI pH1000 OC Standard Serial Number: B399

Serial Number	Fr	Fp	Rp
B399	2180	3753	1.731



B3992180375317310238

NOTE: These criteria are specific for the pH1000 paired with the QC Standard as stated above. The Fr and Fp values must be within 5% of the listed value. The Rp value must be within 1% of the listed value.

USER:				
	Date QC Standard imp	lemented (barcode scanned))

EXPIRY[†]: One (1) year from date of barcode scan

USER: Record the expiry date on the SQC label.

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Steve Geelhood Business Director Date

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