

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

Certificate of Compliance

Date of Manufacture: 12 July 2022

Product Name: BCSI pH SAFE Reader (pH1000TM)

Part Number: 400001

Lot Number: 2207010[†]

BCSI pH1000 Serial Number: BCS0804P0075

BCSI pH1000 QC Standard Serial Number: B442

Serial Number	Fr	Fp	Rp
B442	2825	2987	1.137



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":	
Date QC Standard implemented (barcode scanned)		One (1) year from date of barcode scar

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.

	Quality
D	ISO 13485 ISO 9001
DEKRA Cortified	www.dekro-seal.com

Steve Geelhood **Business Director** 12 Ju122

400001-07



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

Certificate of Compliance

Date of Manufacture: 12 July 2022

Product Name: BCSI pH SAFE Reader (pH1000TM)

Part Number: 400001

Lot Number: 2207010[†]

BCSI pH1000 Serial Number: BCS0804P0081

BCSI pH1000 QC Standard Serial Number: B443

Serial Number	Fr	Fp	Rp
B443	2267	2108	0.810



B4432267210808100205

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.

	Quality
	ISO 13485 ISO 9001
DEKRA Corrified	www.dekro-seal.com

Steve Geelhood Business Director Date

400001-07



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

Certificate of Compliance

Date of Manufacture: 12 July 2022

Product Name: BCSI pH SAFE Reader (pH1000TM)

Part Number: 400001

Lot Number: 2207010[†]

BCSI pH1000 Serial Number: BCS0804P0104

BCSI pH1000 QC Standard Serial Number: B444

Serial Number	Fr	Fp	Rp
B444	2415	2515	0.995



B4442415251509950095

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:	$EXPIRY^{\dagger}$:	:	
Date QC Standard implemented (barcode scanned)		One (1) year from date of barcode scar	

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.

	Quality
	ISO 13485
	ISO 9001
DEKRA	
- contilled	www.dekra-seal.com

Steve Geelhood Business Director Date

400001-07