DECLARATION OF CONFORMITY

ELITechGroup
WESCOR®
370 West 1700 South
Logan, Utah 84321 USA
435 752 6011
800 453 2725
fax 435 752 4127
web www.wescor.com

Manufacturer's Name: Wescor, Inc

Manufacturer's Address: 370 West 1700 South
Logan, Utah 84321-5294
USA

European Authorized Representative: **MT Promedt Consulting, GmbH**
Altenhofstr. 80
D-66386 St. Ingbert / Germany
Tel.: +49 6894 - 58 10 20
Fax: +49 6894 - 58 10 21
www.mt-procons.com

Declares, according to Directive 98/79/EC on *in vitro* diagnostic medical devices, Annex III, the product

Product Name: ChloroChek™

Model Number: 3400

Type of Equipment: AC line-powered, Sweat Chloride Analyzer

IVDD Classification: Other/General
The product is not included in the Annex II List A or List B and is not for self-testing.

The following standards are applied.

IEC 62366:2007
IEC 62304:2006
IEC 61326-1:2005
IEC 61326-2:2005
IEC 61010-1:2001
IEC 61010-2-101:2002
DIN EN 375:2001
DIN EN 980:2008

And was tested for compliance to safety standards:

UL 61010-1 2nd Edition
CSA-C22.2 No. 61010-1-04

Conforms to the Essential Requirements of the In-Vitro Diagnostic Medical Devices Directive 98/79/EC and therefore bears the CE Mark.

Dawn D. Perdue
Dawn Perdue,
Director QA/RA

11 Feb 2013
Date

This Declaration applies to the instrument itself and to the accessories and supplies listed hereafter, which are considered in the assessment of Conformity to the Essential Requirements and which may be shipped with the instrument or by separate order for use with the instrument.

Accessories and Supplies:

AC-071	Ampule Organizer for Sweat Controls
AC-178	Pipette, 10 µL fixed volume
SS-150	Sweat Controls; L1, L2, L3 (12ea; 36 0.75 mL ampules)
SS-248	ChloroChek Reagent Set; Acid-buffer solutions (37x10mL vials) and stabilizer (1x30 mL vial)
SS-251	ChloroChek Standard Solution 100 mmol/L NaCl (10x1 mL ampules)
SS-253	Pipette tips for 10 µL pipette, box of 960 tips