

459 SOUTH MAIN STREET
LOGAN, UTAH 84321 USA
435 752 6011 ■ 800 453 2725
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Manufacturer's Name: Wescor, Inc
Manufacturer's Address: 459 South Main Street
Logan, Utah 84321-5294
USA

**DECLARATION
of
CONFORMITY**

declares, the product

Product Name: Macroduct® Sweat Collection System
Model Number: 3700-SYS
Type of Equipment: Battery-powered device used to induce sweat by iontophoresis.

conforms to the applicable sections of the European Union Council Directive concerning medical devices — 93/42/EEC and as a result complies with:

EN55011/CISPR11(1991) (Emissions) RF Emissions Group 1, Class A
EN50082-1(1992) (Immunity)
EN61000-4-2(1991) ESD — 8 kV Air Discharge, 4 kV Contact Discharge
EN61000-4-3(1984) RF Immunity — 3 V/m
and
EN60601-1 (1990) (Safety)

therefore bears the CE Marking as a Class IIA medical device. Certificate issued by Notified Body BSI, 0086.

This declaration applies to the instrument itself and to the accessories and supplies listed hereafter.

Burt
Name
Director, QA/RA
Title
6/10/04
Date
Logan, Utah USA
Place

Macroduct Sweat Collection System Model 3700-SYS

Accessories and Supplies

SS-032	Macroduct Supply Kit (for 6 sweat tests; contains Pilogel® Disc (12 each), Macroduct Sweat Collector (6 each), Small Sealable Container (6 each)).
SS-032-ND	Macroduct Supply Kit, no dye (for 6 sweat tests; contains Pilogel® Disc (12 each), Macroduct Sweat Collector with no dye (6 each), Small Sealable Container (6 each)).
SS-107	Small Sealable Containers (6 each)
SS-128	Macroduct Strap, Small, 14 cm (replaces RP-083)
SS-129	Macroduct Strap, Medium, 18 cm (replaces RP-084)
SS-130	Macroduct Strap, Large, 25 cm (replaces RP-085)
SS-131	Macroduct Strap, Extra Large, 39 cm (replaces RP-086)
SS-132	Macroduct Strap Set (4 straps, 1 of each size; replaces RP-087)
SS-142	Macroduct (collector only, 1 each; replaces SS-042)
SS-142-ND	Macroduct, no dye (collector only, 1 each; replaces SS-042)