

EC DECLARATION OF CONFORMITY



BIOMEDICAL SYSTEMS

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Manufacturer's Name:

ELITechGroup Inc.
 (d.b.a. Wescor, Inc.)

Manufacturer's Address:

370 West 1700 South
 Logan, Utah 84321 USA

European Authorized Representative:

MT Promedt Consulting, GmbH
 Altenhofstr. 80
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Declares, under sole responsibility, that the follow product,

Product Name: Macroduct[®] Accessories
Item Number: See List Below
Type of Equipment: Accessories used with Macroduct Model 3700 inducer to induce and collect sweat.
MDD Classification: Class I

Conform to the applicable sections of the European Union Council Directive concerning medical devices, MDD 93/42/EEC and therefore bear the CE Marking as Class I medical devices.

Catalog Number	Description	GMDN Code
RP-065	Sweat Dispenser	15128
RP-066	Macroduct Tubing Nippers	15128
RP-381	Black electrode strap for 3700-SYS	15128
RP-382	Red electrode strap for 3700-SYS	15128
RP-383	Pos/Neg, red/black, electrode assy, 3700-SYS	15128
SS-255	Macroduct Strap, Small 3 cm diameter, 20 cm length	15128
SS-256	Macroduct Strap, Medium 6 cm diameter, 28 cm length	15128
SS-257	Macroduct Strap, Large 9 cm diameter, 40 cm length	15128
SS-258	Macroduct Strap, X-Large 13 cm diameter, 68 cm length	15128
SS-259	Macroduct Strap Set (1 ea: S, M, L, XL)	15128

And therefore bears the CE Marking.

A technical file is maintained at ELITechGroup Inc. Biomedical System Division located at 370 West 1700 South, Logan, Utah, 84321, USA and a copy is provided to our European Authorized Representative.



Dawn T. Perdue

19 Jan 2017

Logan, UT USA

Dawn T. Perdue
 Director of Quality Assurance

Date

Location