

EC DECLARATION OF CONFORMITY



Manufacturer's Name: ELITechGroup Inc.

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

European Authorized Representative: **MT Promed Consulting, GmbH**
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Declares, under sole responsibility, that the following Class I items that are part of the Macroduct Advanced Supply Kits (SS-268 and SS-268-ND),

Item Description: Small Sealable Containers
GMDN code: 60298

Item Description: Macroduct Advanced Collector Assembly, NoDye
GMDN Code: 60298

Item Description: Macroduct Advanced Collector Assembly
GMDN Code: 60298

Type of Equipment: Supplies used to collect and transport sweat samples for the Cystic Fibrosis (CF) analysis with Macroduct® Advanced Model 3710.

Conforms to the applicable sections of the European Union Council Directive concerning medical devices, MDD 93/42/EEC, and is classified as a Class I medical device and therefore bears the CE Marking as a Class I medical device.

As such, this item 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.



Stacey Pahulu
Director of Quality Assurance

01/25/2018
Date

Logan, UT
Location