EC DECLARATION OF CONFORMITY

Manufacturer's Name:	ELITechGroup Inc. SRN: US-MF-000006942
Manufacturer's Address:	370 West 1700 South Logan, Utah 84321, USA Tel.: +1 435 752-6011 Fax: +1 435 213-2108
European Authorized Representative:	**MT Promedt Consulting, GmbH** Ernst-Heckel Straße 7 66386 St. Ingbert Germany Tel.: +49 6894 - 58 10 20 Fax: +49 6894 - 58 10 21 www.mt-procons.com SRN: DE-AR-000000085

This declaration is issued under the sole responsibility of the manufacturer, that the following products:

Product Name:	Macroduct® Advanced Supply Kit, Qty 6
Model Number:	SS-268
Basic UDI-DI:	3661540MacroductAdvF7
Intended Purpose:	For use with Macroduct Advanced Sweat Collection System to induce sweat for diagnosis of Cystic Fibrosis.
UDI-DI	03661540304378
GMDN Code:	15128
CND Code:	Z12080408
Device Classification:	Class III

Product Name:	Macroduct® Advanced Supply Kit, w/o Dye, Qty 6
Model Number:	SS-268-ND
Basic UDI-DI:	3661540MacroductAdvF7
Intended Purpose:	For use with Macroduct Advanced Sweat Collection System to induce sweat for diagnosis of Cystic Fibrosis.
UDI-DI	03661540304385
GMDN Code:	15128
CND Code:	Z12080408
Device Classification:	Class III

Product Name:	Macroduct® Advanced Supply Kit, Qty 6
Model Number:	SS-032
Basic UDI-DI:	3661540MacroductAdvF7
Intended Purpose:	For use with Macroduct Sweat Collection System to induce sweat for diagnosis of Cystic Fibrosis.
UDI-DI	03661540302152
GMDN Code:	15128
CND Code:	Z12080408
Device Classification:	Class III

Product Name:	Macroduct® Supply Kit, w/o Dye, Qty 6
Model Number:	SS-032-ND
Basic UDI-DI:	3661540MacroductAdvF7
Intended Purpose:	For use with Macroduct Sweat Collection System to induce sweat for diagnosis of Cystic Fibrosis.
UDI-DI	03661540302169
GMDN Code:	15128
CND Code:	Z12080408
Device Classification:	Class III

covered by this present declaration conform to the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices, associated General Safety and Performance Requirements as set out in Annex I, and RoHS 2 Directive, (2011/65/EU).

Conformity assessment was performed following the requirements of Annex IX, and CE Certificate 755197 issued under supervision of Notified Body, BSI CE 2797.

The following standards were applied:

EN ISO 13485:2016
EN ISO 14971:2019 + A11 :2021
IEC 62366-1:2015
EN ISO 15223-1:2021

And therefore, bears the CE Marking.

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

CE
2797

Robert Ortiz
Regulatory Affairs Manager
On Behalf of ELITechGroup Inc.

2024-05-21
Date

Logan, Utah
Location