

**Manufacturer's Name:** ELITechGroup Inc.  
SRN: US-MF-000006942

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[www.mt-procons.com](http://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 Sweat Collection System  
**Model Number:** 3710  
**Basic UDI-DI:** 3661540MacroAdvInducerS5

**Intended Purpose:** The Macroduct Advanced Model 3710 Sweat Collection System is intended only for clinical laboratory use by qualified medical personnel for stimulation and collection of sweat from humans for analysis for the diagnosis of cystic fibrosis.

**UDI-DI** 03661540304347  
**GMDN Code:** 15128  
**CND Code:** Z12080408  
**Device Classification:** Class IIa

**Product Name:** Macroduct® Advanced Electrode Cable Assembly  
**Model Number:** AC-203  
**Basic UDI-DI:** 3661540MacroAdvInducerS5

**Intended Purpose:** For use with Macroduct Advanced Sweat Collection System to induce sweat for diagnosis of Cystic Fibrosis.

**UDI-DI** 03661540300370  
**GMDN Code:** 15128  
**CND Code:** Z12080408  
**Device Classification:** Class IIa

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).

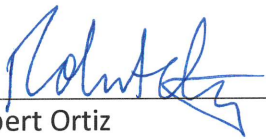
Conformity assessment was performed following the requirements of Annex IX, and CE Certificate 755196 issued under supervision of Notified Body, BSI CE 2797.

The following standards were applied:

EN ISO 13485:2016	IEC 60601-1:2005+Corr. 1:2006 + Corr. 2:2007 + A1:2012
EN ISO 14971:2019 + A11 :2021	IEC 60601-1-2:2014+AMD1:2020
IEC 62366-1:2015	
IEC 62304:2006/AMD1 :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.



Robert Ortiz  
Regulatory Affairs Manager  
On Behalf of ELITechGroup Inc.

2024-05-21

Date

Logan, Utah

Location