

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 755197 R000

**Manufacturer:** ELITechGroup Inc.

**Address:**

370 West 1700 South  
Logan  
Utah  
84321  
USA

**Single Registration Number:** US-MF-000006942

**EU Authorised Representative:** MT Promedt Consulting GmbH

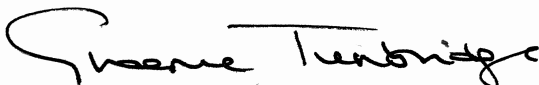
**Address:**

Ernst-Heckel-Straße 7  
66386 St. Ingbert  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-04-24**

Current Issue Date: **2024-04-24**

Starting Validity Date: **2024-04-24**

Expiry Date: **2029-04-23**

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### Device Schedule:

#### Intended Purpose as per the Instructions for Use:

The Macroduct Supply Kits are intended for use with Macroduct Sweat Collection System to induce sweat for diagnosis of Cystic Fibrosis.

The Macroduct Advanced Supply Kits are intended for use with Macroduct Advanced Sweat Collection System to induce sweat for diagnosis of Cystic Fibrosis.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
Macroduct Advanced Supply Kit	SS-268	MDA 0306	Class III	3661540MacroductAdvF7
Macroduct Advanced Supply Kit, w/o dye	SS-268-ND	MDA 0306	Class III	3661540MacroductAdvF7
Macroduct Supply Kit	SS-032	MDA 0306	Class III	3661540MacroductAdvF7
Macroduct Kit, w/o dye	SS-032-ND	MDA 0306	Class III	3661540MacroductAdvF7

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.

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## Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
Current	3497071	Issued



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