

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 755196 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

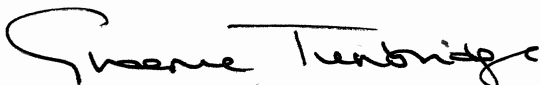
Address:

Ernst-Heckel-Straße 7
66386 St. Ingbert
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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: Class III and Class IIb devices

Class III	Intended purpose
Macroduct Advanced Supply Kit	See MDR 755197
Macroduct Advanced Supply Kit, w/o dye	See MDR 755197
Macroduct Supply Kit	See MDR 755197
Macroduct Kit, w/o dye	See MDR 755197

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Devices for non-invasive, non-sterile, iontophoretic transdermal administration of substances and collection of sweat	Class IIa

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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)

Date	Reference Number	Action
Current	3497069	Issued



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Page 3 of 3

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
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