

ELITechGroup Inc.
370 West 1700 South
Logan, UT 84321 USA
Tel: +1 435 752 6011
Fax: +1 435 752 4127
www.elitechgroup.com



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Supply Disruption: Macroduct[®] Supply Kit, Macroduct[®] Advanced Supply Kit, and Nanoduct[®] Supply Kit

Dear Customers and Distribution Partners,

ELITechGroup Inc. (EGI) is presently unable to import additional Macroduct Supply Kits REF SS-032, Macroduct Advanced Supply Kits REF SS-268, and Nanoduct Supply Kits REF SS-043 into the European Union due to the new Medical Device Regulation (EU MDR 2017/745). CE Certification to the new MDR for the Macroduct Advanced Sweat Collection System Model 3710 SYS is not complete and timing for formal CE Certification is uncertain. The buffer stock of Supply Kits in the ELITech warehouse in France is completely exhausted. There is a limited number of Supply Kits available in stock with ELITech European Distribution Partners and as a result, there likely will be a disruption in supply. EGI is unable to recommend alternative methods of testing.

Background:

In 2019, to prepare for the MDR transition, EGI began communicating potential supply chain disruptions in Europe should recertification to the new MDR regulation take longer than expected. In 2020, EGI prepared to stock additional Supply Kits in its French warehouse and encouraged all partners to increase their stock of Supply Kits due to uncertainties of the CE Certification process. In 2021, EGI increased its buffer stock of Supply Kits in its French warehouse just prior to the final MDR implementation deadline, announced a potential discontinuation of Nanoduct and Macroduct, encouraged its distribution partners to increase their stock of Supply Kits, and recommended customers transition to Macroduct Advanced. In 2022, due to the cost and complexities of the MDR certification process, EGI formally discontinued the Nanoduct Neonatal Sweat Analysis System and the Macroduct Sweat Collection System in Europe.

EGI anticipated CE Certification of Macroduct Advanced Sweat Collection System including Macroduct Advanced Supply Kit and Macroduct Supply Kit would take six to nine months. EGI has now been working on CE Certification to the MDR for more than four years, and formally with its Notified Body for more than one year. Unfortunately, CE Certification is not complete and the buffer inventory of Supply Kits is exhausted.

Next Steps:

EGI continues to work with its Notified Body to recertify the Macroduct Advanced Sweat Collection System, Macroduct Advanced Supply Kit, and Macroduct Supply Kit. There is risk that the Macroduct Supply Kit REF SS-032 will not be accepted as part of the CE Certification process for the Macroduct Advanced. EGI has escalated its concerns to its Notified Body, European Authorized Representative, European Cystic Fibrosis Society (ECFS), KOLs in Europe, CF Societies, and industry groups to raise awareness of the potential disruption of Supply Kits and the impact the disruption will have on Sweat Testing and CF diagnosis in Europe. In addition, EGI is in contact with Ministries of Health throughout Europe in an attempt to obtain a temporary exemption granting authorization to import additional Supply Kits until formal CE Certification is approved and granted.

Summary:

The following table summarizes the current situation.

REF	Description	MDR CE Certification Status	Future Availability of Supply
Nanoduct SYS 1030	Nanoduct Neonatal Sweat Analysis System	Not Applicable	Discontinued in EU
SS-043	Supply Kit for Nanoduct	Not Applicable	Discontinued in EU, Limited remaining supply with EU Distributors
Model 3700-SYS	Macroduct Sweat Collection System	Not Applicable	Discontinued in EU
SS-032	Macroduct Supply Kit	ELITechGroup is working to recertify this Supply Kit with the recertification of the Macroduct Advanced. It is unclear if the Notified Body will recertify this Supply Kit with the Macroduct Advanced submission.	Limited remaining supply with EU Distributors, Risk of future supply.
Model 3710-SYS	Macroduct Advanced 3710 Sweat Collection System	EGL is actively working with its Notified Body to recertify Macroduct Advanced.	Current raw material supply chain constraint, Available Q4 2022, Pending MDR CE Certification Approval Q4 2022
SS-268	Macroduct Advanced Supply Kit	EGL is actively working with its Notified Body to recertify Macroduct Advanced Supply Kit.	Limited remaining supply with EU Distributors, Pending MDR CE Certification Approval Q4 2022

EGL acknowledges the disruption and is doing its best to navigate the regulatory barriers so Macroduct Advanced and Macroduct Advanced Supply Kits are available for use. Please escalate any concerns to the local CF Societies and Ministries of Health in an effort to find a solution. ELITechGroup has worked to provide excellent products to enable an effective diagnosis of Cystic Fibrosis for more than 40 years. The company remains committed to this effort and continues to do its best to make these products available in all global markets.

Best Regards,



Bryce McEuen
Vice President, Biomedical Systems
ELITechGroup Inc.