# ELITech Group B.V. 9/20/17

U.S. FOOD & DRUG ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

**WARNING LETTER**
**SEP 20, 2017**

VIA UNITED PARCEL SERVICE

Christoph Gauer
CEO
ELITech Group SAS
Rue Jean Jaures 13 -15
Puteaux, France 92800

Dear Mr. Gauer:

During an inspection of your firm located in Spankeren, The Netherlands on March 27, 2017, through March 30, 2017, an investigatorfrom the United States Food and Drug Administration (FDA) determined that your firm manufactures the Selectra Pro S, Selectra Pro M and Viva Junior Analyzer devices. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response from Mr. Maurice A.S.V.E. Verdaasdonk, Managing Director dated April 19, 2017, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, which was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to adequately establish and maintain procedures for corrective and preventive action activities (CAPA) and failure to adequately document CAPA results as required by 21 CFR 820.100. For example:

a) Your firm's CAPA procedure, P73 V08.0 "CAPA Procedure", (multiple versions reviewed) does not include documented instructions covering the practice of postponing CAPAs. In addition, your procedure does not include the requirement for CAPA information to be disseminated to the individuals affected.

b) During the review of your firm's CAPA several deficiencies were noted, e.g., CAPA #239 was opened on 04/01/2016 as a result of an external audit finding associated with your firm's trending for products complaints. Trending did not take into account (potential) problems other than those related to dead on arrival devices and there is no evidence based on output of service activities to show that your top management was made aware of the complaint trending. Your CAPA was postponed on 11/04/2016 due to your site not having the budget. There was no documented investigation and/or assessment of whether temporary corrections could be put in place to mitigate the issue. Your CAPA record states that the CAPA was closed on 11/04/2016; however, your Management Representative indicated that the CAPA was actually in a postponed stage and was reopened on 12/22/2016 and remains opened.

Your firm's response dated April 19, 2017, is not adequate. Your firm provided a draft Remediation Plan (Gantt chart) outlining task and stated that you will provide detailed responses by Observation, with supporting documentation, approximately on a monthly basis. However, to date, no response or documentation has been submitted. Your firm's response(s) should include a description and evidence of implementation of corrections and corrective actions, which must consider systemic problems, to address this observation.

2. Failure to adequately establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820.198. For example:

a) Your firm's complaint procedure, P67, "Complaint handling" (multiple versions reviewed) does not include the following requirements:

- A requirement that oral complaints are documented upon receipt;
- A requirement that when a complaint is not investigated, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate;

- A requirement that the record of investigation shall include: the name of the device; the date the complaint was received; any unique device identifier (UDI), and any other device identification(s) and control number(s) used; the name, address, and phone number of the complainant; the nature and details of the complaint; the dates and results of the investigation; any corrective action taken; and any reply to the complainant.

b) Review of complaint files revealed that complaints were not investigated. For example: Complaint #3861 dated 11/09/2016, associated with the sample syringe on the ProM showing rusty residue was not investigated, Complaint #3913 dated 12/28/2016 associated with the **(b)(4)** and power connector being burnt out on the ProM Analyzer was not investigated, leaking unit Complaints #3475 and #3480 dated 09/04/2015 and 09/09/2015 respectively, associated with the Viva Junior Analyzer; Complaint #3208 and #3209 dated 09/25/2014, associated with the ProS Analyzer; and Complaint #3200 dated 09/16/2014, associated with the ProS Analyzer were not investigated.

c) A Management Representative explained that your U.S. sister site, does not communicate complaints to your firm unless they are unable to resolve the issue. However your firm's SOP requires that the U.S. sister site notifies your firm of any instrument related complaint within five working days. Your firm did not follow its own quality agreement in which your firm have documented complaint handling responsibilities and that required your U.S. sister site reports all instrument related complaints to your firm.

Your firm's response dated April 19, 2017, is not adequate. Your firm provided a draft Remediation Plan (Gantt chart) outlining task and stated that you will provide detailed responses by Observation, with supporting documentation, approximately on a monthly basis. However, to date, no response or documentation has been submitted. Your firm's response(s) should include a description and evidence of implementation of corrections and corrective actions, which must consider systemic problems, to address this observation.

3. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test that the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a). For example, your firm did not validate your water system installed in 2010 which produces the purified water that is used for final product testing of the clinical analyzers (i.e., ProM, ProS, etc.), production of reagents, production of solution system, and other functional tests.

Your firm's response dated April 19, 2017, is not adequate. Your firm provided a draft Remediation Plan (Gantt chart) outlining task and stated that you will provide detailed responses by Observation, with supporting documentation, approximately on a monthly basis. However, to date, no response or documentation has been submitted. Your firm's response(s) should include a description and evidence of implementation of corrections and corrective actions, which must consider systemic problems, to address this observation.

4. Failure to adequately establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR 820.50. For example:

a) Your firm's purchasing control procedure, P41, "The classification of suppliers", (multiple versions reviewed) does not include quality requirements that must be met by suppliers to ensure that they are able to deliver product according to specifications. In addition, your procedure does not include requirements for how external audits will be conducted and also how your firm will follow up with suppliers exceeding the vendor rating analysis (1%

threshold) which includes assessing the number of return parts. During the review of your firm's 2015 - 2016 quarterly vendors rating, a number of suppliers with over 10 returned parts exceeding the 1% threshold were noted and your firm did not follow up with the suppliers in any of these cases except for one firm.

b) Your firm did not qualify your supplier for the **(b)(4)**(PCBA board), on their ability to meet quality requirements. **(b)(4)** is used in the **(b)(4)** of the clinical analyzers to keep **(b)(4)**. The only document available on file was the quotation document and supplier qualification card. It was noted during this inspection that the **(b)(4)** was the part which was most replaced in 2016 (17 total). According to the record since January 2014, there have been 22 complaints associated with a malfunctioning **(b)(4)** board.

Your firm's response dated April 19, 2017, is not adequate. Your firm provided a draft Remediation Plan (Gantt chart) outlining task and stated that you will provide detailed responses by Observation, with supporting documentation, approximately on a monthly basis. However, to date no response or documentation has been submitted. Your firm's response(s) should include a description and evidence of implementation of corrections and corrective actions, which must consider systemic problems, to address this observation.

5. Failure to adequately establish and maintain procedures for acceptance of incoming product, to be adequately inspected or tested to verify conformance to specification as required by 21 CFR 820.80 (b). For example, your firm did not implement adequate incoming acceptance activities for the Printed Circuit Boards (PCB) used within the clinical analyzer to ensure they meet specifications. Specifically, your firm's incoming acceptance activities for the PCB include; warehouse employee inspecting for box damage, quantity count, and comparing the purchase order to the delivery note. The PCB supplier conducts testing of PCBs for your firm; however, during acceptance activities, your firm did not receive any documentation (Certificate of Analysis or test results) from the supplier indicating that the tests were conducted and your firm did not inspect or test the PCBs at any stage within production to ensure the specifications were met, except for a functional test perform on the **(b)(4)**. For example, the following PCB shipments: **(b)(4)** shipment received on 12/16/2016; **(b)(4)** shipment received on 01/10/2017; and System board shipment received on 01/30/2017 were accepted based on an inspection of box damage, quantity count, comparing the purchase order to the delivery note without inspecting, reviewing any test results or conducting any test to verify conformance to specification.

Your firm's response dated April 19, 2017, is not adequate. Your firm provided a draft Remediation Plan (Gantt chart) outlining task and stated that you will provide detailed responses by Observation, with supporting documentation, approximately on a monthly basis. However, to date no response or documentation has been submitted. Your firm's response(s) should include a description and evidence of implementation of corrections and corrective actions, which must consider systemic problems, to address this observation.

6. Failure to adequately establish and maintain procedures for installation and inspection instructions, and where appropriate, test procedures as required by 21 CFR 820.170(a). For example, your firm did not follow its own procedure, P65, "Installation and qualification of devices", (multiple version reviewed) which states that service personnel (distributors) should fill out and return completed installation and qualification reports after installation of an automatic analyzer (i.e. Pro M, Pro S, etc.). Since 2011, out of the **(b)(4)**(Pro M and Pro S) installed in the United States by your firm's sister site, only **(b)(4)** installation and qualification reports were returned. Your firm's System Support Manager confirmed that installation/qualification reports for these units installed in the United States market were not always returned.

Your firm's response dated April 19, 2017, is not adequate. Your firm provided a draft Remediation Plan (Gantt chart) outlining task and stated that you will provide detailed responses by Observation, with supporting documentation, approximately on a monthly basis. However, to date, no response or documentation has been submitted. Your firm's response(s) should include a description and evidence of implementation of corrections and corrective actions, which must consider systemic problems, to address this observation.

7. Failure to adequately establish and maintain procedures for quality audits as required by 21 CFR 820.22. For example, your internal quality audit procedure, P715 "Internal Quality audits" (multiple version reviewed) is inadequate as the procedure allows your firm to utilize your customer audits conducted at your firm's facility instead of your firm conducting its own internal audits at all times. It was noted during the review of your firm's internal audit plans from 2012 - 2016, that instead of your firm conducting internal audits of all areas mentioned in your plans you counted the external audits conducted during this time frames as your "internal audit" of those areas. Specifically, your 2014 audit plan for the following procedures; P66 Handling of repair and warranty parts procedure and P67 Complaint Handling were audited by your firm's customer **(b)(4)**. Additionally, in 2016, procedure P81 Software Validation for software used in processes was audited by **(b)(4)**. However, your firm's procedure does not explain how customer audits substitute your firm's internal audits to ensure that the external customer audit will focus on the quality system being in compliance with the established quality system requirements.

Your firm's response dated April 19, 2017, is not adequate. Your firm provided a draft Remediation Plan (Gantt chart) outlining task and stated that you will provide detailed responses by Observation, with supporting documentation, approximately on a monthly basis. However, to date, no response or documentation has been submitted. Your firm's response(s) should include a description and evidence of implementation of corrections and corrective actions, which must consider systemic problems, to address this observation.

Our inspection also revealed that your firm's Selectra Pro S, Selectra Pro M and Viva Junior Analyzer devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant violations include, but are not limited to, the following:

Failure to adequately develop and maintain written MDR procedures, as required by 21 CFR 803.17. After reviewing your firm's MDR procedure titled "Work Instruction W711-03 – Incident Reporting and Product Recall – US" (Doc No.: W711-03, Version: V04.0, Effective Date: 23-Mar-2017), the following issues were noted:

1. W711-03, Version: V04.0 does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the following are not addressed:

a. Your firm should adjust your MDR procedure accordingly to include a process for submitting MDRs electronically in accordance with the Final Rule for electronic Medical Device Reporting (eMDR) published in the Federal Register on February 14, 2014. In addition, if your firm has not established an eMDR account in order to submit MDRs electronically, your firm should do so as soon as possible.

2. W711-03, Version: V04.0, does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example:

a. Your procedure includes the definition for the term “MDR reportable event” found in 21 CFR 803.3. Your procedure omits definitions of the terms “become aware,” “serious injury,” ”malfunction,” and “caused or contributed” from 21 CFR Part 803.3 and the definition for the term “reasonably suggests,” found in 803.20(c)(1). The exclusion of the definitions for these terms from the procedure may lead your firm to make an incorrect reportable decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a).

3. W711-03, Version: V04.0, does not establish internal systems that provide for a standardized review process to determine when an event meets the criteria for reporting under this part. For example:

a. There are no instructions for conducting a complete investigation of each event and evaluating the cause of the event.

b. Your procedure, as written does not specify who makes the decision for reporting events to FDA.

c. There are no instructions for how your firm will evaluate information about an event to make MDR reportable determinations in a timely manner.

4. W711-03, Version: V04.0, does not describe how your firm will address documentation and record-keeping requirements, including:

a. Documentation of adverse event related information maintained as MDR event files.

b. Information that was evaluated to determine if an event was reportable.

c. Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable.

d. Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

The adequacy of your firm’s response dated April 19, 2017, cannot be determined at this time. Although, your firm’s response states that corrections are planned, in progress, or even completed, and your statements appear to be adequate from a technical perspective, your firm did not include all of the documentation or evidence for the activities listed in the Remediation Project Plan (ref. Gantt QMS Remediation Plan – 20170419 dated April 17, 2017). Your firm’s response should include a description and evidence of implementation of corrections and corrective actions, which must consider systemic problems, to address this observation.

Our inspection also revealed that your firm's Selectra Pro S, Selectra Pro M and Viva Junior Analyzer devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 806 – Medical Device; Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

1. Failure to submit any report required within 10-working days of initiating a correction or removal, as required by 21 CFR Part 806.10. For example, your firm failed to report the following corrections or removals to FDA: a) field correction involving the replacement of a power supply related to REV7 of power supply 3359-048 initiated March 22, 2012, and b) field correction involving software update (V1.2.5) for V-Twin Analyzer with bar Code Reader Initiated February 1, 2016.

Your firm's response dated April 19, 2017, is not adequate. Your firm provided a draft Remediation Plan (Gantt chart) outlining task and stated that you will provide detailed responses by Observation, with supporting documentation, approximately on a monthly basis. However, to date, no response or documentation has been submitted. Your firm's response(s) should include a description and evidence of implementation of corrections and corrective actions, which must consider systemic problems, to address this observation.
U.S. federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective action (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review. We will notify you regarding the adequacy of your firm's responses and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 3540, 10903 New Hampshire Ave., Silver Spring, MD 20993. **Refer to CMS case # 534429 when replying.** If you have any questions about the contents of this letter, please contact: Rebecca Keenan at telephone (301-796-6215)or fax (301-847-8515).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.