

16 May 2018

Maria Bevenko  
Association of Medicine and Analytics Co Ltd  
199034, 4-6, 17 Liniya V.O.  
Saint-Petersburg  
Russia

Dear Maria:

I am writing to inform you we have notified the Competent Authority in the following countries:

- **The Netherlands\***

With this notification, Association of Medicine and Analytics Co Ltd has met the requirements of the In-vitro Diagnostics Directive, 98/79/EC for the following devices:

- **AMA RUT Pro**

As of today and without any further notice from the respective Competent Authorities, Association of Medicine and Analytics Co Ltd can consider the respective devices as officially notified.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,



Rene van de Zande  
Director  
Emergo Europe

*\* Self-Certify/Other IVD notification in The Netherlands with the Dutch Healthcare Inspectorate (IGZ) grants you access to: Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Switzerland, Sweden, and the United Kingdom.*



**Emergo Europe B.V.**

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*After notification in the Netherlands, the following countries still require additional notification for Self-Certify/Other: Belgium and Croatia. Please let us know if Association of Medicine and Analytics Co Ltd will require notification in any of the additional countries.*

*\* List A, List B and Self-Test IVD notification in The Netherlands with the Dutch Healthcare Inspectorate (IGZ) grants you access to: Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Slovakia, Slovenia, Sweden, Switzerland, and the United Kingdom.*

*After notification in the Netherlands, the following 8 countries still require additional notification for higher IVDs: Belgium, Croatia, Italy, Latvia, Portugal, Romania, and Spain. Please let us know if Association of Medicine and Analytics Co Ltd will require notification in any of the additional countries.*