

C E p a r t n e r 4 U

Certificate number: 2016-IVD/CE159

Certificate of CE-Notification

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

Technology-Standard Ltd
116/95, Kalinin Prospekt,
Barnaul, 656037
Russia

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by **CEpartner4U** as listed on the product list attached to the manufacturer's Declaration of Conformity:

IVD devices were registered under number:

Group : Kits and reagents for in vitro diagnostics of haemostasis system

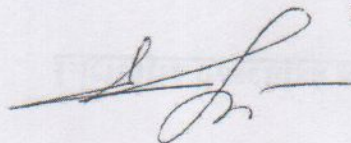
Notification No.: NL-CA002-2015-34420

see appendix

with Dutch Competent Authorities as a consequently these IVD devices were entered in EUDAMED by Dutch Competent Authorities

The manufacturer has provided **CEpartner4U** with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

Issue date: 2016-08-19



Olga Teirlinck
Consultant **CEpartner4U BV**

C E p a r t n e r 4 U

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CERTIFICATE

No. 71191



This is to certify the Quality Management System of Medical Devices of



«Technology-Standard» LTD
116/95, Kalinin Prospekt
656037 City of Barnaul
Russia

has been assessed and found to be in compliance with the Standard

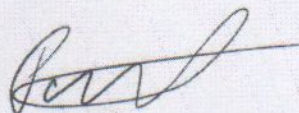
EN ISO 13485:2016

applicable to

Development, production and sales of diagnostic kits and reagents for in vitro diagnostics of hemostasis system.



The certificate has been issued under No. **71191** for the registration period from 05 August 2019 to 04 August 2022.
The first certificate date of issue is 05 August 2016.


Approved by


Printed by



validity code **658F2782-225**

Check the validity of this certificate using this code at www.ll-c.info