

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

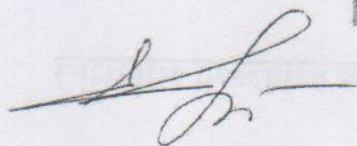
Notification No.: NL-CA002-2015-34420

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

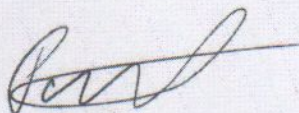
EN ISO 13485:2016

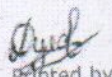
applicable to

**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