

## DECLARATION OF CONFORMITY

Declaration of Conformity

Document ref.: D○C2015

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1) Manufacturer (Name, department): "Technology-Standard" Ltd

Address: 116/95, Kalinin Prospekt, Barnaul, 656037, Russia and

2) European authorized representative: **CEpartner4U BV**,

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS, [www.cepartner4u.eu](http://www.cepartner4u.eu))

3) **Pr○dUCT(s)** (name, type or model/batch number, etc.):

- **K i t s** and reagents for in vitro diagnostics of haemostasis system see *appendix*

4) The product(s) described above is in conformity with:

| Title                                                | Document No. |
|------------------------------------------------------|--------------|
| <i>In vitro</i> Diagnostic Medical Devices Directive | 98/79/EC     |

5) Additional information (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.): **Conformity**

assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : **NL-CA002-2015-34420**

Barnaul, Russia; 2015-03-17

(Place & date of issue (yyyy-mm-dd))

Andrey Momot, Director "Technology-Standard" Ltd

(name; function and signature of manufacturer)



Declaration form: Standard ISO/IEC 17050-1:2010

vs. 2011-x

## Appendix

Date: 2015-02-09

Declaration of Conformity

List of devices.

| Device name                                                                                                        | Type/ model/ref number              | Risk class | Code:EDMS/GMDN 1      | First date of CE-compliance |
|--------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------|-----------------------|-----------------------------|
| «Techplastin-test»<br>The kit of reagents for the determination of prothrombin time                                | 607,<br>131,<br>608,<br>140,<br>735 | Low        | 13 02 01 01/<br>30539 | 09.02.2015                  |
| «SFMC-test»<br>The kit of reagents for the determination of soluble fibrin monomer complexes in blood plasma       | 081,<br>007                         | Low        | 13 02 03 03/<br>43421 | 09.02.2015                  |
| «APTT-test»<br>The kit of reagents for the determination of activated partial thromboplastin time                  | 152,<br>001                         | Low        | 13 02 01 02/<br>32392 | 09.02.2015                  |
| «Tech-Fib rinogen-test»<br>The kit of reagents for the determination of fibrinogen concentration in blood plasma   | 324,<br>094,<br>225                 | Low        | 13 02 02 01/<br>30541 | 09,02.2015                  |
| «ChromoTech-Plasminogen»<br>The kit of reagents for the determination of plasminogen concentration in blood plasma | 092                                 | Low        | 13 02 05 05/<br>30578 | 09.02.2015                  |

See EDMS codes: <http://www.edma-ivd.be/> (products classification)/Preference GMDN code



| Device name                                                                                                          | Type/ model/ref number | Risk class | Code:EMDS/GMDN 1      | First date of CE-compliance |
|----------------------------------------------------------------------------------------------------------------------|------------------------|------------|-----------------------|-----------------------------|
| «ChromoTech-Antithrombin»<br>The kit of reagents for the determination of antithrombin concentration in blood plasma | 192                    | Low        | 13 02 06 02/<br>33156 | 09.02.2015                  |
| «Calibrtaor universal»<br>The kit of control blood plasma for the study of haemostasis                               | 773                    | Low        | 13 02 50 02/<br>30590 | 09.02.2015                  |
| «Thrombo-test»<br>The kit of reagents for the determination of thrombin time                                         | 151,<br>609,<br>610    | Low        | 13 02 01 03/<br>30540 | 09.02.2015                  |
| «Tech-Factor VIII- test»<br>The kit of reagents for the determination of factor VIII activity in blood plasma        | 274                    | Low        | 13 02 02 07/<br>30547 | 09.02.2015                  |
| «PARUS-test»<br>The kit of reagents for the determination of disorders in protein C system                           | 164                    | Low        | 13 02 06 08/<br>30588 | 09.02.2015                  |
| «APTT-EI-test»<br>The kit of reagents for the determination of activated partial thromboplastin time                 | 649,<br>652            | Low        | 13 02 01 02/<br>32392 | 09.02.2015                  |
| «Soluble thromboplastin with calcium»<br>A reagent for determination of prothrombin time                             | 643,<br>638            | Low        | 13 02 01 01/<br>30539 | 09.02.2015                  |
| «Thrombin»<br>A reagent for the study of haemostasis                                                                 | 323,<br>017            | Low        | 13 02 01 03/<br>30540 | 09.02.2015                  |

| Device name                                                                                                                              | Type/ model/ref number | Risk class | Code:EMDS/GMDN 1      | First date of CE-compliance |
|------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------|-----------------------|-----------------------------|
| «Tech-Factor IX-test»<br>The kit of reagents for the determination of factor IX activity in blood plasma                                 | 679                    | Low        | 13 02 02 08/<br>30548 | 09.02.2015                  |
| «RNP-plasma»<br>Reference normal pooled plasma                                                                                           | 774                    | Low        | 13 02 50 02/<br>30590 | 09.02.2015                  |
| «Pathoplasma»<br>Pathologic plasma                                                                                                       | 775                    | Low        | 13 02 50 02/<br>32394 | 09.02.2015                  |
| «Techplastin-test (K)»<br>The kit of reagents for the determination of prothrombin time, prothrombin ratio and INR in blood              | 144                    | Low        | 13 02 01 01/ 30539    | 09.02.2015                  |
| <(Tech-Antithrombin-test»<br>The kit of reagents for the determination of antithrombin III activity                                      | 688                    | Low        | 13 02 06 02/<br>33156 | 09.02.2015                  |
| «Lupus-test»<br>The kit of reagents for the determination of anticoagulants of lupus type                                                | 011                    | Low        | 13 02 06 07/<br>30587 | 09.02.2015                  |
| «Express-Lupus-test»<br>The kit of reagents for the determination of lupus anticoagulant                                                 | 193                    | Low        | 13 02 06 07/<br>30587 | 09.02.2015                  |
| «Fibrinolysis-test»<br>The kit of reagents for the study of Xlla-kininogenase-dependent, spontaneous and induced euglobulin fibrinolysis | 009                    | Low        | 13 02 05 90/<br>0     | 09.02.2015                  |

| Device name                                                                                                                                   | Type/ model/ref number | Risk class | Code:EMDS/GMDN 1      | First date of CE-compliance |
|-----------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------|-----------------------|-----------------------------|
| «MultiTech-Fibrinogen»<br>The kit of reagents for the determination of fibrinogen concentration by automated and semi-automated coagulometers | 711,<br>712            | Low        | 13 02 02 01/<br>30541 | 09.02.2015                  |
| «Fibrinogen-Calibrator»<br>The kit of calibrators for the determination of fibrinogen concentration                                           | 714                    | Low        | 13 02 50 02/ 39413    | 09.02.2015                  |
| «ADP»<br>The kit of reagents for the determination of ADP-aggregation of platelets                                                            | 030                    | Low        | 13 02 04 01/<br>30569 | 09.02.2015                  |
| Ristomycin<br>The kit of reagents for the determination of ristomycin-aggregation of platelets                                                | 197                    | Low        | 13 02 04 01/<br>30569 | 09.02.2015                  |
| «Collagen»<br>The kit of reagents for the determination of collagen-aggregation of platelets                                                  | 095                    | Low        | 13 02 04 01/<br>30569 | 09.02.2015                  |
| «Adrenaline»<br>The kit of reagents for the determination of adrenaline- aggregation of platelets                                             | 031                    | Low        | 13 02 04 01/<br>30569 | 09.02.2015                  |

| Device name                                                                                  | Type/ model/ref number | Risk class | Code:EMDS/GMDN<br>1   | First date of CE compliance |
|----------------------------------------------------------------------------------------------|------------------------|------------|-----------------------|-----------------------------|
| «Aggrescreen-test»<br>The kit of reagents for the express assessment of platelet haemostasis | 010                    | Low        | 13 02 04 01/<br>30569 | 09.02.2015                  |
| «Human platelets»                                                                            | 132                    | Low        | 13 02 04 01/<br>32409 | 09.02.2015                  |
| «Sodium citrate»<br>A reagent for the stabilization of blood in the study of haemostasis     | 028                    | Low        | 13 02 80 02/<br>0     | 09.02.2015                  |