CEpartner4U

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

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Olga Teirlinck
Consultant CEpartner4U BV

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