



OOO NPP TECHNOMEDICA

## EC Declaration of Conformity

### Product Identification

Product name: Portable Photometrical Hemoglobinometer for measurement of total blood hemoglobin by means of the hemiglobincyanide method

Model/Type: PPH-03/540 "MiniHEM"

### Manufacturer

Name: OOO NPP TECHNOMEDICA

Address: Building 1, 43 Sel'skokhozyaystvennaya Street, Moscow, 129323

Country: Russia

### Authorized Representative in Europe

Name: Wellkang Ltd

Address: Suite B, 29 Harley Street, London, W1G 9QR

Country: England, United Kingdom

OOO NPP TECHNOMEDICA hereby declares that the product listed is in conformity with the Annex III, essential requirements and provisions of the Council Directive

### 98/79/EC

on *in vitro* diagnostic medical devices

and is in conformance with the following harmonised standards:

**EN 61010-2-101: 2002**

**EN 61326-2-6: 2006**

**EN ISO 18113-3: 2011**

**EN 980: 2008**

**EN ISO 14971: 2012**

This Declaration is only valid when the product is used in accordance to the "Instruction for Use" and becomes void if the device is modified without our consent.

Place and Date: OOO NPP TECHNOMEDICA October 1, 2014

Signature:

Name:

Nikolay Ovanesov  
General Director

