



OOO NPP TECHNOMEDICA

EC Declaration of Conformity

Product Identification

Product name: Portable Photometrical Hemoglobinometer for measurement of total blood hemoglobin by means of the modified oxyhemoglobin method
Model/Type: PPH-03/523 "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

