



Declaration of Conformity EC

We:

Hydrex Diagnostics Sp. z o.o. Sp. komandytowa
ul. Tomasza Zana 4, 04-313 Warszawa
Poland

certify and declare on our own responsibility that the following products:

HX Serowhites 5
HX Serowhites 6
HX Serowhites 7
HX Serowhites 8
HX Serowhites 9
HX Serowhites 10
HX Serowhites 11
HX Serowhites 12

comply with all Essential Requirements (Annex I) of the European Directive 98/79/CE for in vitro medical devices.

The aforementioned products are not listed in Annex II and therefore this declaration fulfils the self-declaration requirements of Annex III (excluding point 6).

All supporting documentation is retained under the premises of the manufacturer who considers the following standards: PN-EN ISO 13485, PN-EN ISO 14971, PN-EN ISO 18113-1, PN-EN ISO 18113-2, PN-EN ISO 15223-1, PN-EN 13612, PN-EN 23640, PN-EN 13641.

Warszawa, August 29th, 2016

Tomasz Stasik
Managing Director