HYDREX

EC Declaration of Conformity

Manufacturer: Hydrex Diagnostics Sp. z o.o.
Aleja Stanów Zjednoczonych 61A
04-028 Warszawa
Polska

ensures and declare on our own responsibility that an in vitro diagnostic medical device for professional use listed below

Products:		***Catalog No:***	
	HX Serowhites 5		**HXSB5, SPR000045**
	HX Serowhites 6		**HXSB6, HXSB6E**
	HX Serowhites 7		**HXSB7, SPR000044**
	HX Serowhites 8		**HXSB8**
	HX Serowhites 9		**HXSB9, HXSB9E**
	HX Serowhites 10		**HXSB10, SPR000043**
	HX Serowhites 11		**HXSB11**
	HX Serowhites 12		**HXSB12, HXSB12E**

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

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

Medical Devices Management System

ISO 13485:2016-04 Certyfikat Nr M – 38-a/8/2022

ISO 13485:2016-04 Certyfikat Nr M – 38-b/8/2022

This declaration of conformity is valid for the period of validity of the certificate

All supporting documentation is retained under the premises of the manufacturer who considers the following standards:

PN-EN ISO 13485:2016-04	PN-EN ISO 18113-1:2011	PN-EN 13612:2006
PN-EN ISO 14971:2020-05	PN-EN ISO 18113-2:2011	PN-EN 13641:2006
PN-EN ISO 23640:2015-10	PN-EN ISO 18113-3:2011	PN-EN 15223-1:2022-01

Deklaracja ważna do: 05.05.2025