

## 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*

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

**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

  
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Dyrektor Zarządzający