

## EC Declaration of Conformity

Manufacturer's name:	<b>Norma Instruments Zrt.</b>
Headquarters:	Papírgyár u. 58-59., 1038 Budapest, Hungary
Products:	<b>Hemolyzer<sup>®</sup> 5 NG (closed mode)</b>
REF.- Number:	<b>HE5100</b>
Directives:	<p>98/79/EC on <i>in vitro</i> diagnostic medical devices (IVD)            Classification: General/Other IVD – Outside Annex II and not for self-testing</p> <p>2011/65/EU on restriction of hazardous substances (ROHS)            Classification: Category 8 Medical Device</p> <p>2015/863/EU amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances</p> <p>2014/30/EC on electromagnetic compatibility (EMC)</p> <p>2014/35/EC on low voltage (LVD)</p>
Standards:	<p>MSZ EN 13612:2007, MSZ EN ISO 14971:2020, MSZ EN ISO 15223-1:2022, MSZ EN ISO 18113-1:2012, MSZ EN ISO 18113-3:2012, MSZ EN 50581:2013, EN 55011:2016, MSZ EN 60825-1:2014/A11:2021 EN 61000-3-2:2019, EN 61000-3-3: 2013 + A1:2019, MSZ EN 61010-1:2011, MSZ EN 61010-2-101:2017, EN 61326-1: 2013, MSZ EN 61326-2-6:2013, EN 62304:2006, MSZ EN 62366-1:2015</p>

We, **Norma Instruments Zrt.**, do herewith declare under our sole responsibility that the **CE marked** In Vitro Diagnostic Medical Device

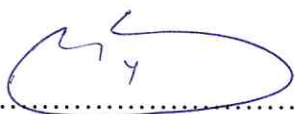
### **Hemolyzer<sup>®</sup> 5 NG (closed mode)**

is in conformity with the Essential Requirements of **Annex I** and with the requirements listed in **Annex III** by the **Directive 98/79/EC** on *in vitro* diagnostic medical devices (*IVD Directive*),

and is in conformity with the requirements of the harmonized quality management system of **EN ISO 13485:2016**.

Budapest, 2022/05/16

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 Gergely Domonkos Horváth  
 Chief Executive Officer  
 Norma Instruments Zrt.

