EC Declaration of Conformity

Manufacturer's name:	**Norma Instruments Zrt.**
Headquarters:	Papírgyár u. 58-59., 1038 Budapest, Hungary
Products:	**Hemolyzer® 5 NG (closed mode)**
REF.- Number:	**HE5100**
Directives:	98/79/EC on *in vitro* diagnostic medical devices (IVD) Classification: General/Other IVD – Outside Annex II and not for self-testing 2011/65/EU on restriction of hazardous substances (ROHS) Classification: Category 8 Medical Device 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 2014/30/EC on electromagnetic compatibility (EMC) 2014/35/EC on low voltage (LVD)
Standards:	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

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

Hemolyzer® 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

NORMA INSTRUMENTS Zrt.
1038 Budapest
Papírgyár u. 58-59.
Adószám: 24742159-2-41

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Gergely Domonkos Horváth
Chief Executive Officer
Norma Instruments Zrt.

CE

Digitally signed by Goreacii Vitalie
Date: 2023.10.18 11:47:04 EEST
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