DECLARATION OF CONFORMITY

No.: XX/2021

The undersigned, representing the following manufacturer

Manufacturer:	**Diatron MI Plc.**
Address:	**H-1097 Táblás u. 39, Budapest, Hungary**

herewith declares that below product

Product identification:	**Autopak 300 clinical chemistry autoanalyzer for in vitro determinations with optional ISE module**
Product code:	**APK300**
Power requirements:	**110/240 V, 50/60 Hz, 600 VA**

is in conformity with the provisions of the following Directive(s)
(including all applicable amendments)

Reference No.	Title
98/79/EC	**In vitro diagnostic medical devices** General IVD device, other than listed in IVDD Annex II and other than intended for self-testing

and that the <u>standards and/or technical specifications referenced overleaf have been applied</u>.

Year of first affixing the CE marking: 2019

Budapest, 26-04-2021

Diatron MI Zrt.
1097 Budapest, Táblás u. 39.
adószám: 13863326-2-43
telefon: +36 1 436 9800
16.
diatron

István Lacik
General Manager

(name and function of the signatory empowered to bind the manufacturer or his authorized representative)

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References of harmonized standards and/or technical specifications applied for this declaration of conformity, or parts thereof:

No.	issue	Title
EN ISO 13485	2016	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 15223-1	2016	Symbols to be used with medical devices labels
EN ISO 15193	2009	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for content and presentation of reference measurement procedures
EN ISO 15194	2009	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for certified reference materials and the content of supporting documentation
EN 13612	2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 14971	2012	Application of risk management to medical devices
EN 61010-2-101	2012	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-1	2013	Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements
EN 61326-2-6	2013	Electrical equipment for measurement, control and laboratory use – EMC requirements Part 2-6: : Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 62304:2006+A1	2015	Medical device software. Software life-cycle processes
IEC 62366-1	2015	Medical devices. Application of usability engineering to medical devices.
EN ISO 18113-1	2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 1: Terms, definitions and general requirements
EN ISO 18113-3	2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 3: In vitro diagnostic instruments for professional use.

- **other technical solutions, the details of which are included in the technical documentation or the technical construction file:**

Other references or information required by the applicable EC directive(s): EN 61010-1 is published under LVD (2014/35/EC) and *EN 61326* is published under EMCD (2014/30/EC), ROHS2 (2011/65/EU), thus this product is in conformity with the essential requirements of these directives, too.