Date: 23/05/2022

EC Declaration of Conformity according to Annex IV of the In Vitro Diagnostic Regulation 2017/746 (IVD)

This is to certify that the IVD product listed in attachment is manufactured by D-tek s.a. Rue René Descartes, 19. B-7000 Mons, Belgium

- The products comply with all General safety and performance requirements (Annex I) of the regulation 2017/746 on In Vitro Diagnostic Medical Devices.
  This compliance has been properly documented using a checklist created from Annex I and supported by technical documentation according to Annexes II and III.
- D-tek s.a. has a certified Quality System in place based on the ISO 13485 standard.
- This Declaration of Conformity is signed below, certifying that the requirements of the regulation 2017/746 and the above applicable regulations and directives have been met and documented.

For the BlueDiver Instrument 1 (BLUEDIVER1):

- 2017/746 RIVD on in vitro diagnostic devices Regulation
- 2014/30/EU EMC Electromagnetic Compatibility Directive
- 2014/35/EU LVD Low Voltage Directive
- 2012/19/EU WEEE on waste Electrical and electronic equipment
- 2011/65/EU RoHs-2 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
  - Applied Standards:
    - IEC61326-1
    - IEC61326-2-6
    - IEC61010-1
    - IEC61010-2-101

For the BlueDiver Instrument 2 (BLUEDIVER2):

- 2017/746 RIVD on in vitro diagnostic devices Regulation
- 2014/30/EU EMC Electromagnetic Compatibility Directive
- 2014/35/EU LVD Low Voltage Directive
- 2012/19/EU WEEE on waste Electrical and electronic equipment Directive
- 2011/65/EU RoHs-2 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Directive
  - Applied Standards:
    - IEC61326-1
    - IEC61326-2-6
    - IEC61010-1
    - IEC61010-2-101
    - IEC61010-2-010

For the BlueScan scanner (BLUESCAN1 + DR DOT LIC4)

Scanner:

- 2017/746 RIVD on in vitro diagnostic devices Regulation
- 2014/30 UE EMC Electromagnetic Compatibility Directive
- 2012/19 EC WEEE on waste Electrical and electronic equipment Directive
- 2011/65/EC RoHs-2 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Directive

Software

- 2017/746 RIVD on in vitro diagnostic devices Regulation

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CE REGISTRATIONS

IVDR 2017/746 EC – Art. 17

Instruments :

Product Code	Intended Use	EC Notification Number	Basic UDI-DI	Risk Class	REF/Trade Name
BLUEDIVER1	*Semi-automated ImmunoAssay Instrument dedicated to the carrying out of in vitro diagnosis tests. It performs the various steps of incubation and washing of D-tek's immunodot strips and other kits with equivalent BlueDiver Design (strips and cartridges), from the deposit of the sample to the final colour development. The BlueDiver Instrument is intended only for laboratory professional use and must be used only by trained personnel.*	BE/CA01/1-15225-10001-IVD	5425023685006VX	A	BLUEDIVER1 / BlueDiver Instrument AD INSTRUMENTBD/ BlueDiver Instrument 415040 / AUTOPLEX DIA1000 / Neptune Instrument
BLUEDIVER2	*Automated ImmunoAssay Instrument dedicated to the carrying out of in vitro diagnosis tests. It performs the various steps of samples pipetting, incubation, washing, drying and reading of D-tek's immunodot strips, from the deposit of the sample to the final reading of the strips. The instrument can also manage other kits with equivalent BlueDiver design (strips and cartridges)* *The maximum capacity of the Instrument is of 24 strips which are incubated simultaneously.* *The Instrument is intended only for laboratory professional use and must be used only by trained personnel.*	BE/CA01/1-15225-10002-IVD	5425023685044W7	A	BLUEDIVER2 / BlueDiver Instrument 2 AD INSTRUMENTBD2/ BlueDiver Instrument 2 516781 / AUTOPLEX II
BLUESCAN1 + DR DOT LIC4	*The BlueScan Scanner and DrDot Software System is an instrument intended to help the semi-quantitative interpretation of IVD products. The scanner has been specifically developed for the reading of the strips with "BlueDiver" design. Based on the image of the scanned strips, the Dr Dot software converts the intensity of each dot/line into a numerical value. The Bluescan Scanner and Dr Dot software are intended only for laboratory professional use and must be used only by trained personnel*	BE/CA01/1-15225-10003-IVD	5425023685013VU	A	BLUESCAN1/ BlueScan Scanner + DR DOT LIC4/ Dr Dot Software AD SCANBD/BlueDiver Scanner + AD SOFTBD/ DR DOT Software Licence 415051/SCANNER AUTOPLEX + DR DOT LIC4/ Dr Dot Software DIA1003/Neptune Scanner + DIA1001/Neptune Software