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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

- This product complies 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 EN ISO13485 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.

  - 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

Date : 23/05/2022

Benoît AUTEM
Managing and Marketing Director

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CE REGISTRATIONS

IVDR 2017/746 EC – Art. 17

Instruments :

Product Code	Intended Use	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.*	5425023685006VX	A	BLUEDIVER1 / BlueDiver Instrument
				AD INSTRUMENTBD/ BlueDiver Instrument
				415040 / AUTOPLEX
				DIA1000 / Neptune Instrument