We Apply Science

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.

For the BlueScan 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

For the software

- 2017/746 RIVD on in vitro diagnostic devices Regulation

Date : 23/05/2022

Benoît AUTEM
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CE REGISTRATIONS

IVDR 2017/746 EC – Art. 17

Instruments :

Product Code	Intended Use	Basic UD-DI	Risk Class	REF/Trade Name
BLUESCAN1	*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.* .	**5425023685013VU**	A	BLUESCAN1/ BlueScan Scanner
				AD SCANBD/BlueDiver Scanner
				415051/SCANNER AUTOPLEX
				DIA1003/Neptune Scanner
DR DOT LIC4				DR DOT LIC4/ Dr Dot Software
				AD SOFTBD/ DR DOT Software Licence