DIAGAST

EU Declaration of Conformity

(According to Annex IV of the Regulation (EU) 2017/746)

DIAGAST, 251 avenue Eugène Avinée, 59120 Loos, France, SRN FR-MF-000012310, declares that the in vitro medical devices to which this certificate relates are classified as Class D according to the rules set out in the Annex VIII of the Regulation (EU) 2017/746.

Phenotyping devices – Basic UDI: 3661562DPKBGRPHEXXXXXXX5N

Anti-C (PK1)	**REF B10337**
Anti-E (PK1)	**REF B10338**
Anti-c (PK1)	**REF B10339**
Anti-e (PK1)	**REF B10340**
Anti-K (PK1)	**REF B10341**
Anti-C (PK2)	**REF B10342**
Anti-E (PK2)	**REF B10343**
Anti-c (PK2)	**REF B10344**
Anti-e (PK2)	**REF B10345**
Anti-K (PK2)	**REF B10346**

They have been designed, produced and tested according to the essential health and safety requirements and are in conformity with the European standard NF EN ISO 13485 and the Regulation (UE) 2017/746 of the European parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

They comply to common specification for in vitro medical devices in respect to Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laid down for devices intended for detection of blood group antigens in the Rh and Kell blood group system.

G-MED (notified body - n° 0459 - Paris - France) certificates n° 39430 rev.0 (expiry date: March 16th, 2028) and N° 39431 rev.0 (October 18th, 2028) according to the conformity assessment procedure set out in the Annex IX of the Regulation (EU) 2017/746.

In consequence of, the CE mark has been affixed on the related devices.

The following EU declaration is issued under DIAGAST's responsibility as manufacturer.

CE 0459

November,7th 2023

Director of Quality & Regulatory Affairs
Ludovic ETCHEVERRY

G MED *NF EN ISO 13485*