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.

Internal quality control device – Basic UDI: 3661562DIQCBGXXXXXXXXXXJB

HEMA CQI **REF 59500**

HEMA CQI is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians as quality control for ABO-RH1 and RH-KEL1 phenotyping in manual or automated method.

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.

G-MED (notified body - n° 0459 - Paris - France) certificates n° 39732 (expiry date: May 5th, 2024) and n° 39430 (expiry date: March 16th , 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

May 16th, 2024

Chief Executive Officer
Olivier BROLLI

Signé par Olivier BROLLI - Président Directeur Général
Le 16/05/24
Signed with Universign