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 A according to the rules set out in the Annex VIII of the Regulation (EU) 2017/746.

Basic UDI: 3661562ALISSXXXXXXXXXXXXQ

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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 are intended to prepare human red blood cell suspensions in combination with other IVMDs to perform various immunohematology-related tests.

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

December 12th, 2023

Chief Executive Officer
Olivier BROLLI