



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: 3661562AEMTAUTOMATEXXXXX7

QWALYS INSTRUMENT REF 90870

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 perform blood grouping, red cell phenotyping, antibody screening and identification, direct antiglobulin tests and/or crossmatching assays, in donor or patient samples.

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