DIAGAST

EC Declaration of Conformity

DIAGAST declares that the in vitro medical device to which this certificate relates:

QWALYS® 3 **REF 90854**

has been designed, produced and tested according to the essential health and safety requirements and is in conformity with the European Directives and European standards following:

98/79/EC
Directive of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices: Annex III - EC Declaration of conformity.

2014/30/EU
Directive on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

2014/35/EU
Directive on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

2011/65/EU
Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

NF EN 61326-1: 2012, 61326-2-6: 2013
Electrical equipment for measurement, control and laboratory uses - EMC requirements.
Part 1: General requirements
Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

NF EN 61010-1: 2011, 61010-2-081: 2015, 61010-2-101: 2017
Safety requirements for electrical equipment for measurement, control and laboratory use.
Part 1: General requirements
Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other uses
Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

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

December 01st, 2021/ 01 décembre 2021

Chief Executive Officer/*Président Directeur Général*

(Olivier BROLLI)

NF EN ISO 13485

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