



DIAGAST

EC Declaration of Conformity

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

QWALYS® 3

REF 90804

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: 2006, 61326-2-6: 2006

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: 2001, 61010-2-081: 2003, 61010-2-101: 2003

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