



# Conformity Declaration

DiaSys Diagnostics India Private Limited

Plot No. A-821, TTC, MIDC· Mahape, Navi-Mumbai, 400710· Maharashtra,  
India

Declares conformity of the product

## QDx Malaria Pv/Pf

Cat no.: 400295506 – 25 Tests  
400295501 – 10 Tests

according to the essential requirements Annex I of the Directive 98/79/EC on in vitro diagnostic medical devices (IVD Directive). The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III of the Directive 98/79/EC (product grouping common/other IVD products), except of Point 6.

DiaSys Diagnostics India Private Limited

04.04.2018

  
Bertrand de Castelnaud  
CEO



<b>EC REP</b>	DiaSys Diagnostic Systems GmbH
	Alte Strasse 9
	65558 Holzheim
	Germany

Registration No. : DE/CA 32 DIA 2/3588

**List of applied standards for products of  
DiaSys Diagnostic Systems GmbH  
Alte Strasse 9  
65558 Holzheim**

**Applied Directives:**

**98/79/EC** Directive 98/79/EC on in vitro diagnostic medical devices (IVD Directive).

**For analyser additional**

**2011/65/EU** Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

**Applied Standards**

**General:**

**EN ISO 13485** Medical devices - Quality management systems - Requirements for regulatory purposes  
**EN ISO 14971** Medical devices – Application of risk management to medical devices  
**EN ISO 15223-1** Medical devices Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements  
**EN 62366** Medical devices – Application of usability engineering to medical devices

**Reagents**

**EN 13612** Performance evaluation of in vitro diagnostic medical devices  
**EN 13641** Elimination or reduction of risk of infection related to in vitro diagnostic reagents  
**EN 13975** Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects  
**EN ISO 17511** In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials  
**EN ISO 18113-1** In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements  
**EN ISO 18113-2** In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use  
**EN ISO 23640** Stability testing of in vitro diagnostic reagent

**Note:** Standards are used in the actual issue or as listed in the latest "List of harmonized standards" according Directive 98/79/EC.