



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 PAN/Pf

Cat no.: 400295507 – 25 Tests
400295503 – 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 Castelnau
CEO



<table border="1"> <tr> <td style="padding: 5px;">EC</td> <td style="padding: 5px;">REP</td> </tr> </table>	EC	REP	DiaSys Diagnostic Systems GmbH
	EC	REP	
	Alte Strasse 9		
	65558 Holzheim		
Germany			

Registration No. : DE/CA 32 DIA 2/3609

**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.