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 Trop I

Cat no.: 400295508 10 Tests
400295548 10 Tests (mono cartons)

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

CE

EC REP	DiaSys Diagnostic Systems GmbH
	Alte Strasse 9
	65558 Holzheim
	Germany

Registration No. : DE/CA 32 DIA 2/3590

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.