Eurotrol

Your Global Reference Point for Quality Control

EU Declaration of Conformity

(in accordance with standard EN ISO/IEC 17050-1)

Manufacturer
Eurotrol B.V.
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The Netherlands

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Product Family
253
CueSee® tHb

Product(s)

Product Code	Description
253.001.002	CueSee® tHb - Level 1
253.002.002	CueSee® tHb - Level 2
253.003.002	CueSee® tHb - Level 3

The product(s) of the declaration described above is/are in conformity with the requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Classification
'Other', not listed in Annex II

- Method of Assesment: Self-Assesment according to ANNEX III

These products are manufactured conforming our procedures that meet the following Standard:

Standard	First Date of Issue	Current Certificate Expiry Date
EN-ISO 13485:2012	2003-09-01	2018-07-01

Declared by
Ede, 2015-07-01

Paul B.P. Kooijmans
Regulatory Affairs Manager

Bart H. Maas
Managing Director