Eurotrol
Your Global Reference Point for Quality Control

Declaration of Conformity

Manufacturer Eurotrol B.V.
Keplerlaan 20
6716BS Ede
The Netherlands
(+31)0318695777

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product(s)	REF Number	Name	Intended Use
	146.001.002	Eurotrol GlucoTrol-NG Level 1	Eurotrol GlucoTrol-NG is an assayed glucose control intended for professional use in the verification of the precision and accuracy of the HemoCue® Glucose Systems.
	146.002.002	Eurotrol GlucoTrol-NG Level 2	
	146.003.002	Eurotrol GlucoTrol-NG Level 3	
	146.004.002	Eurotrol GlucoTrol-NG Level 4	
	146.005.002	Eurotrol GlucoTrol-NG Level 5	

Means of conformity	The product(s) of the declaration described above is/are in conformity with the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices and the transitional provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 as amended by Regulation (EU) 2022/112.
Classification	Other in-vitro medical devices (Article 9(1) of Directive 98/79/EC), handled as Class C device with regards to the transitional provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 as amended by Regulation (EU) 2022/112.
Method of Assessment	Conformity assessment according to Annex III of Directive 98/79/EC.
References	The product(s) of the declaration described above is/are manufactured according to procedures which meet EN-ISO 13485:2016.
Valid until	2027-05-26

Declared by

Place and date: Ede,

Name and function: D. Philippens, QA/RA Director

Signature:

Eurotrol B.V.
P.O. Box 722, 6710 BS Ede, Keplerlaan 20, 6716 BS Ede, The Netherlands, T +31 318 695777, office@eurotrol.com, www.eurotrol.com, ABN AMRO Bank No. 56.18.38.909, BIC ABNANL2A, IBAN NL92ABNA0561838909, Trade register Arnhem 09067367, VAT No.NL009139448B01