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
	179.001.010	Eurotrol GAS-ISE Metabolites Level 1	Eurotrol GAS-ISE Metabolites is an assayed blood gas, electrolyte and metabolite reference material, to verify the precision and accuracy of the epoc® Blood Analysis System. Eurotrol GAS-ISE Metabolites was designed to test the following analytes: pH, pO_2, pCO_2, Na^+, K^+, Ca^{++}, Mg^{++}, Cl^-, Glucose, Lactate, Urea, Creatinine and tCO_2.
	179.002.010	Eurotrol GAS-ISE Metabolites Level 2	
	179.003.010	Eurotrol GAS-ISE Metabolites Level 3	

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.
Classification	Other in-vitro medical devices (Article 9(1) of Directive 98/79/EC).
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	2022-05-25

Declared by

Place and date: Ede, 23 Jun 2020

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

Signature:

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