Eurotrol
Your Global Reference Point for Quality Control

Declaration of Conformity

Manufacturer Eurotrol B.V.
Keplerlaan 20
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The Netherlands
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This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product(s)	REF Number	Name	Intended Use
	022.001.002 022.002.002 022.003.002	Eurotrol HemoTrol Low (Level 1) Eurotrol HemoTrol Normal (Level 2) Eurotrol HemoTrol High (Level 3)	Eurotrol HemoTrol® is an assayed quality control material for professional use to verify the performance characteristics of the HemoCue Hb 201 systems. HemoTrol® is intended for the quantitative determination of hemoglobin.

Means of conformity	The products of the declaration described above 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 products of the declaration described above are manufactured according to procedures which meet EN-ISO 13485:2016.
Valid until	2027-05-26

Declared by

Place and date: Ede, 16 May 2022

Name and function: Daniel Philippens, QA/RA Director

Signature:

Eurotrol B.V.
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