

# Declaration of Conformity

## Manufacturer

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Email: info@vivachek.com www.vivachek.com

## European Representative

Lotus NL B.V.  
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.  
Tel: +31644168999 E-mail: peter@lotusnl.com

## Product Name

Myoglobin/CK-MB/Troponin I Combo Rapid Test

## Classification:

Other device, not in annex II, not for self-testing, not for performance evaluation.

Conformity assessment procedure: ANNEX III, 98/79/EC

We hereby declare that the above mentioned products meet the COUNCIL DIRECTIVE 98/79/EC and applicable standards. All supporting documentations are retained in the manufacturer and EU representative.

## General applicable standards:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Hangzhou, China, 23 May 2022

Place, Date of issue



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