

Certifikat d.o.o.  
GOSPODARSKA ZONA 15  
32000 VUKOVAR  
Croatia

## DECLARATION OF CONFORMITY

**Certificate d.o.o.** manufactures and sells ready to use microbiological substrates for "in vitro diagnostics". Production is in compliance with the quality management system certified by SGS Adriatica d.o.o. certificate number HR11 / 0498 and certificate number CH11 / 0631. The production is in accordance with the following standards and normative documents:

- HRN EN ISO 9001: 2015 Quality management systems
- HRN EN ISO 14001: 2015 Environmental Management Systems
- EN ISO 13485: 2012, ISO 13485: 2016 Quality Management System for Medical Products
- Medicinal Products statute (NN 76/13)
- Ordinance on Essential Requirements, Classification, Quality System, Enrollment in Producer Inventory and Medical Devices Register and Assessment of Conformity of Medical Devices (NN 84/13). The products are not covered by List A and List B in Annex II for "in vitro" diagnostics of this ordinance (Article 8, paragraph 2).

This statement confirms that the products manufactured are in accordance with:

Directive 98/79 / EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical products (SL L 331, 7.12.1998).

Technical documentation is kept in our premises, under the responsibility of quality assurance manager.

Certificate d.o.o., Gospodarska zona 15, 32000 Vukovar, Croatia hereby declares that the products are manufactured in accordance with the above mentioned documents.

In Vukovar, 06.03.2019

A handwritten signature in blue ink is written over a circular blue stamp. The stamp contains the text 'CERTIFIKAT d.o.o.', 'VUKOVAR, Gospodarska zona 15', and 'OIB: 38466254572'.

Director:  
mr.sc. Mario Bajto, dipl. oec.