

# DECLARATION OF CONFORMITY

## Nº 014/2022

### Manufacturer

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### European Authorized Representative

UAB «V&D group»  
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Vilnius, Lithuania  
Tel.: + 370 (60) 65-31-86  
E-mail: logistic@vd-group.lt

### Medical device type Intended purpose device

**IN VITRO diagnostic medical device, other medical devices of the kit is intended for** assessing the severity of cervical canal epithelial dysplasia or conducting differential diagnosis of two conditions to evaluate the condition of the cervix by the real-time Polymerase Chain Reaction (PCR) method. The intended users are professional personnel of clinical personnel.

### Product name

#### Kits for liquid-based cytology "NOVAPREP"

Product name	Release form	Catalog number
«NOVAprep-miR-CERVIX»	3	CERVIX-48A
	5	CERVIX-96A

We, the undersigned, hereby declare that the described products meet the essential requirements listed in Directive 98/79/EC of the European Parliament and of the Council dated October 27, 1998. The Technical File required by this Directive is maintained at the Manufacturer's Authorized Representative: UAB "V&D group" 51/412 Paneryu St., LT 03160, Vilnius, Lithuania.

### Standards Applied

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2021 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2016 +AC:2016 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2015 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN ISO 14971:2019 (Medical devices. Application of risk management to medical devices).

### Licence No.

LT/CA01/IVD/014/22

### Licensee

UAB «V&D group», 51/412 Paneryu St., Vilnius

### Start of CE-Marking

**02.06.2022**

### Classification

Other diagnostic medical devices (All devices except Annex II and shelf-testing devices)

### Conformity

#### Assessment Procedure

Annex III  
of the Directive 98/79/EC  
(not including section 6)

Director  
Algimed Techno LLC  
(Minsk, Belarus)



**Vladislav Liutynski**

**Date: 02.06.2022**