NOVAprep®

# DECLARATION OF CONFORMITY № 019/2022


**Manufacturer**

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**EC REP European Authorized Representative**

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**Medical device type Intended purpose device**

**IN VITRO diagnostic medical device: Automated system for liquid based cytological diagnostics NOVAPREP Processor System.**
NOVAPREP products are designed for use with liquid cytology applications. NOVAPREP HQ + Orange Vial - is a vial intended to be used with NOVAPREP Processor System (NPS 25 или NPS 50) for cervical cancer screening. Automated NOVAPREP Processor System NPS 50 prepares a cell suspension sample contained in NOVAPREP HQ + Orange Vial, into a thin homogeneous cell layer on a slide. Relevant cells and cell clusters are preserved for diagnosis. This automated preparation process includes mixing of the cell suspension, a sedimentation step, pipetting and transfer of cells of interest to a decantation system where cells are allowed to settle onto a glass slide.

**Product name**

**Automated system for liquid based cytological diagnostics «NOVAPREP»**

| Product name | Catalog number |
|---|---|
| «NOVAPREP Processor System NPS 25» | NOV010 |

**Standards Applied**

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.

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), EN 61326-1:2021 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements, EN 61326-2-6:2021 Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment, EN 61010-1: 2010 Safety requirements for electrical equipment for measurement, control and laboratory use- Part 1: General requirements, EN 61010-2-081: 2015 Safety requirements for electrical equipment for measurement, control and laboratory use- Part 2-081: Particular requirements for automatic and semi- automatic laboratory equipment for analysis and other purposes, 61010-2-101: 2017 Safety requirements for electrical equipment for measurement, control and laboratory use- Part 2-101: Particular requirements - In vitro diagnostic (IVD) medical equipment.

**Licence No.** LT/CA01/IVD/019/22

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

| Start of CE-Marking | Classification | Conformity Assessment Procedure |
|---|---|---|
| 18.05.2022 | Other diagnostic medical devices (All devises except Annex II and shelf-testing devices) | Annex III of the Directive 98/79/EC (not including section 6) |

Director
Algimed Techno LLC
(Minsk, Belarus)

*Vladislav Liutynski*

Date: 18.05.2022