NOVAprep®

DECLARATION OF CONFORMITY № 020/2022

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 50»	NOV011

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/020/22

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