NOVAprep®

DECLARATION OF CONFORMITY № 016/2022

Manufacturer

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EC REP 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»	EXT-3 EXT-5	CERVIX-48A 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/016/22

Licensee

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

Start of CE-Marking
02.06.2022

Classification
Other diagnostic medical devices (All devises 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