Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System
No. 14 0005 QS/NB

The quality system of manufacturer

GeneProof a.s.

Vídeňská 101/119, Dolní Heršpice, 619 00 Brno, Czech Republic

has been certified as meeting the requirements of

Directive 98/79/EC

on in vitro diagnostic medical devices, Annex IV excluding (4, 6)

for the following product category(ies):

GeneProof PCR kits and reagents for detection of pathogens *Chlamydia trachomatis*, *Chlamydia pneumoniae*, HIV, HBV, HCV, CMV, and for multiplex detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Mycoplasma genitalium*

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to Annex IV (Section 4) is required.

Valid from: 2022-05-20
Valid until: 2024-01-17
First Issued: 2014-01-20
Revision: i

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Date: 2022-05-20

Mgr. Jiří Heš
Representative of the Notified Body No. 1023