



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

EC Design-Examination Certificate No. 16 0575 CN/NB

issued for manufacturer

GeneProof, a.s.

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

in accordance with requirements of

Directive 98/79/EC

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

for the following product category(ies):

GeneProof PCR kit for detection of pathogen HBV

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. For placing on the market of List A devices covered by this certificate, an EC Certificate according to the Annex IV (excluding sections 4 and 6) is required.

Valid from: 2019-08-29
Valid until: 2024-01-17
First Issued: 2016-12-16
Revision: a



Date: 2019-08-29

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