EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1804149-1

Manufacturer: Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha WI 53186
USA

Digitally signed by Talpiş Andrei
Date: 2024.04.20 11:19:03 EEST
Reason: MoldSign Signature
Location: Moldova

Products: Annex II List B Products:

LIFECODES HLA-A SSO Typing Kit
LIFECODES HLA-A eRES SSO Typing
LIFECODES HLA-B SSO Typing Kit
LIFECODES HLA-B eRES SSO Typing
LIFECODES HLA-DRB1 SSO Typing kit
LIFECODES HLA-DRB1 eRES SSO Typing kit
LIFECODES HLA-DRB 3,4,5 SSO Typing kit
LIFECODES HLA-Null Allele SSO Typing kit

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

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TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.