EC Certificate

TÜVRheinland®

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

Registration No.: HL 1804149-1

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

Products: Replaces CE Certificate, Registration No.: HL 60139674 0001

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.

Report No.: 3333164-560

Effective date: 2020-12-17

Expiry date: 2024-05-26

Issue date: 2020-12-17

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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.