

EC Certificate

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

Registration No.: HL 60139674 0001

Report No.: 60239244 001

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

Products: see attachment for products included

Expiry Date: 2021-01-03

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.

Effective Date: 2019-05-29

Date: 2019-05-29

Notified Body


Dipl.-Ing. Sven Hoffmann



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HL 60139674 0001
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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

LIFECODES HLA Typing Tray Class I (ABC) 72
LIFECODES HLA Typing Tray Class I (ABC) 72C
LIFECODES HLA Typing Tray Class I (ABC) 72BL
LIFECODES HLA Typing Tray Class I (ABC) AB1/AB2
LIFECODES HLA Typing Tray Class I (ABC) ABC1/ABC2
LIFECODES HLA Typing Tray B27 (B27)
LIFECODES HLA Typing Tray Class II (DR) DR

Notified Body



Date: 2019-05-29


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