

EC Design-Examination Certificate
Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60139615 0001

Report No.: 60239284 001

Manufacturer: Immucor, Inc.
3130 Gateway Drive
Norcross GA 30071
USA

Product

Identification:

Control for Immucor low protein Blood Grouping Reagents and gamma-clone® Blood Grouping Reagents used in Slide, Tube, and Microplate Tests

(see attachment for products included)

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2023-04-11

Notified Body

Effective Date: 2019-05-29

Date: 2019-05-28



H. Lüdemann
Dr. H. Lüdemann

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.: IL 60139615 0001
Report No.: 60239284 001

Manufacturer: Immucor, Inc.
3130 Gateway Drive
Norcross GA 30071
USA

Products:

Monoclonal Control

- Catalogue Number 0066087 (1 x 10 mL)
- Catalogue Number 0066089 (10 x 10 mL)

Date: 2019-05-29



Notified Body


Dr. H. Lüdemann