TÜVRheinland®

EC Design-Examination Certificate

Directive 98/79/EC Annex IV, Section 4

In Vitro Diagnostic Medical Devices

Registration No.: IL 60139609 0001

Report No.: 60239279 001

Manufacturer:

Immucor, Inc.
3130 Gateway Drive
Norcross GA 30071
USA

Product Identification:

Control cell for the quality control of Weak D testing

- Weak D Cells

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: 2023-11-30

Effective Date: 2019-05-29

Date: 2019-05-28

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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.