TÜVRheinland®

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

Registration No.: IL 60139610 0001

Report No.: 60239280 001

Manufacturer:

Immucor, Inc.
3130 Gateway Drive
Norcross GA 30071
USA

Product Identification:

Reagent red cells for use in tube and microplate ABO serum grouping 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: 2023-11-30

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.

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TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: IL 60139610 0001
Report No.: 60239280 001

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

Products:

- Referencells-4 (Group A1, A2, B and O)
- Referencells-2 (Group A1 and B)
- Referencells-1 (Group A2)

TÜV Rheinland LGA Products GmbH – TÜVRheinland® – Zertifizierungsstelle

Notified Body

Date: 2019-05-29

Dr. H. Lüdemann

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