

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 60104677 0001

Report No.: 31591092 001

Manufacturer: Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis IN 46268
USA

Products: Products and sites included: see attachment
Replaces Approval, Registration No.: HL 60041595 0001

Expiry Date: 2020-10-13

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: 2015-11-04

Date: 2015-11-04

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 60104677 0001
Report No.: 31591092 001

Manufacturer: Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis IN 46268
USA

Products:

- PTS PANELS[®] Glucose and Clinical Chemistry Test Strips
- CardioChek[®] Brand Analyzers
- PTS PANELS[®] Controls
- A1C Now[®] Self Check

Additional site included:

Polymer Technology Systems, Inc.
510 Oakmead Parkway
Sunnyvale, CA 94085 USA

Scope:

Design/development and manufacture of A1C Now[®] Self Check

Date: 2015-11-04

Notified Body


Dipl.-Ing. Sven Hoffmann

