ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 18 02 78578 007

Manufacturer:
National Diagnostic Products Pty Ltd
7-9 Merriwa Street
Gordon, NSW 2072
AUSTRALIA

EC-Representative:
National Diagnostic Products Pty Ltd
Am Dorbach 12
52076 Aachen
GERMANY

Product Category(ies): **Blood glucose measuring systems for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: **JNQ235032172**

Valid from: **2018-03-29**
Valid until: **2022-02-23**

Date, 2018-03-29

Stefan Preiß

04052767797408

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

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No. V1 18 02 78578 007

Model(s):

Betachek
Betachek C50
Betachek G5
Glucoflex-R

Facility(ies):

National Diagnostic Products Pty Ltd
7-9 Merriwa Street, Gordon, NSW 2072,
AUSTRALIA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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