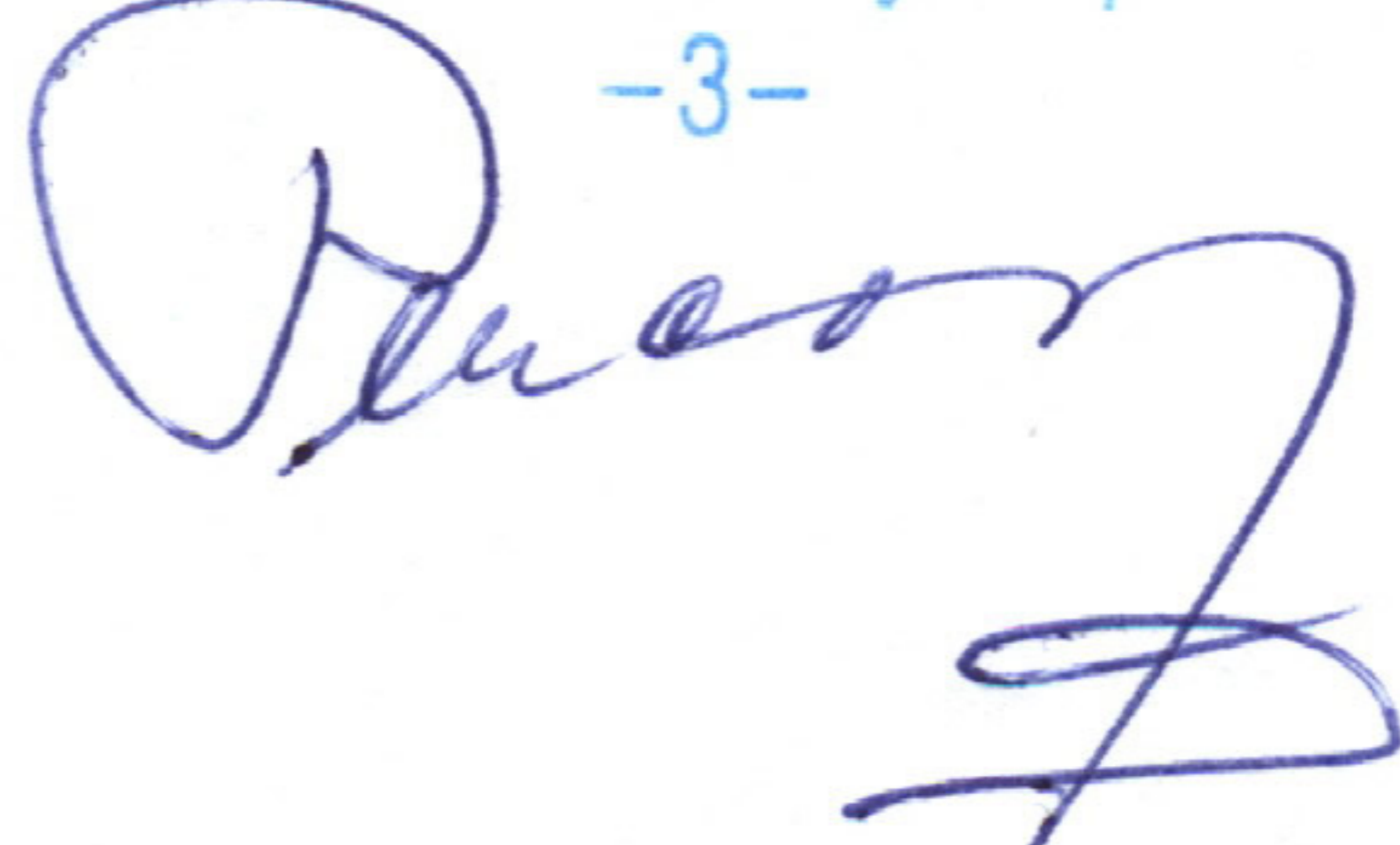


Výstup z databázy kódov registrovaných / evidovaných zdravotníckych pomôcok

K	Kód	Názov	Doplňok	Výrobca
P	83348	IVD - testy Food Detective	samodiagnost. potravinovej intolerancie	CAG-GB

Kód/y ZP podľa aktuálnej  
databázy SÚKL  
Bratislava dňa 27. MÁJ 2009

Štátny ústav pre kontrolu liečiv  
Kvetná 11, 825 08 Bratislava 26  
Sekcia zdravotníckych pomôcok

-3-  


**Upozornenie:**

Tento výstup z databázy kódov registrovaných / evidovaných ZP neslúži ako súčasť žiadosti o zaradenie ZP do zoznamu ZP plne alebo čiastočne uhrádzaných na základe verejného zdravotného poistenia.

Skratku výrobcu predstavujú prvé tri znaky zľava.

# Certificate

The Certification Body of  
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization  
**MediPurpose Pte. Ltd.**  
**300 Beach Road**  
**#38-05, The Concourse**  
**Singapore 199555**  
**Singapore**

has established and applies a quality management system for medical devices  
for the following scope:

**Design, development, manufacture and distribution of  
medical safety lancets**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2003**

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60018998 0001

An audit was performed. Report No.: 15800026 001

This Certificate is valid until: 13.07.2012



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-995.00.01-46

Cologne, 10.10.2007

Certification Body



TÜV Rheinland  
Zertifizierungsstelle

Dipl.-Ing. D. Meier

**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**

Tel.: (+49/221) 806 - 1371 Fax: (+49/221) 806 - 3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**APPROVAL**  
**EC Directive 93/42/EEC Annex II, Article 3**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60018997 0001

**Report No.:** 15800026 001

**Manufacturer:** MediPurpose Pte. Ltd.  
300 Beach Road  
#38-05, The Concourse  
Singapore 199555  
Singapore

**Scope:** Design, development and manufacture of medical  
safety lancets

Replaces Approval, Registration No.: HD 60017836 0001

**Date of Expiry:** 13.07.2012

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Dipl.-Ing. D. Meier

Cologne, 10.10.2007



**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

# Certificate

The Certification Body of  
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

**MediPurpose Pte. Ltd.**  
**300 Beach Road**  
**#38-05, The Concourse**  
**Singapore 199555**  
**Singapore**

has established and applies a quality management system  
for the following scope:

**Design, development, manufacture and distribution  
of medical safety lancets**

Proof has been furnished that the requirements specified in

**EN ISO 9001:2000**

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SY 60018999 0001

An audit was performed. Report No.: 15800026 001

This Certificate is valid until: 13.07.2012

Cologne, 10.10.2007

Certification Body



Dipl.-Ing. D. Meier

**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**

Tel.: (+49/221) 806 - 1371 Fax: (+49/221) 806 - 3935 e-mail:cert-validity@de.tuv.com <http://www.tuv.com/safety>

<b>CAMBRIDGE NUTRITIONAL SCIENCES LTD</b>		
Written By: Dr. J. G. Reeve	Form 21-06a	Rev. No. 03
Approved By: Mr Andrew Shepherd	Effective Date: 13th February 2009	

**EC Declaration of Conformity**  
In accordance with Directive 98/79/EC

We, Cambridge Nutritional Sciences Ltd.

of Eden Research Park, Henry Crabb Road, Littleport, Ely, Cambridgeshire, UK

declare that:

*Product name:* **Food Detective**

*Product number:* **CNSFDR**

in accordance with the following Directive

98/79/EC - The In Vitro Diagnostic Medical Devices Directive

has been designed and manufactured to the following specifications:

(List of harmonised standards, normative references etc. and their titles)

BE EN ISO 14971:2001	Medical Devices – Application of risk management to medical devices
BS EN ISO 9001:2000	Quality systems – Model for quality assurance in design/development, production, installation and servicing
BS EN ISO 13485: 2003	Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001
BS EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
BS EN 13640:2002	Stability testing of in vitro diagnostic reagents
EDMA Code:	12020109
Product Classification:	Self-test
Conformity Assessment:	Annex IV of Directive 98/79EC
Notified Body:	LRQA/0088

I hereby declare that the device named above has been designed to comply with the relevant sections of the above referenced specifications. The device complies with all essential requirements of the Directive.

Signed by:  .....

Name: ANDREW SHEPHERD

Position: Director

Place: Cambridge Nutritional Sciences Ltd

Date: 13<sup>th</sup> February, 2009



## APPROVAL OF CONFORMITY CERTIFICATE

**In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Cambridge Nutritional Sciences Ltd  
Eden Research Park, Henry Crabb Road  
Littleport, Cambridgeshire, CB6 1SE  
United Kingdom**

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 4003829  
Original Approval: 19 April 2007  
Current Certificate: 19 April 2010  
Certificate Expiry: 31 October 2011  
LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



**APPROVAL OF CONFORMITY CERTIFICATE  
CERTIFICATE LRQ 4003829 SCHEDULE**

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

**Cambridge Nutritional Sciences Ltd  
Eden Research Park, Henry Crabb Road  
Littleport, Cambridgeshire, CB6 1SE  
United Kingdom**

**Self-Test Products**

**Food Detective Premium CNSFDGP  
Food Detective CNSFDR  
Food Detective Mini CNSFDM**

Schedule Issue: 1  
Date of Schedule Issue: 19 April 2010  
LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited