Circular Informativa

N.º 094/CD/550.20.001

Data: 30/05/2019

Assunto: **Certificado CE de conformidade falso – Fabricante DB Biotech, Inc.**

Para: Divulgação geral

Contacto: Centro de Informação do Medicamento e dos Produtos de Saúde (CIMI); Tel. 21 798 7373; Fax: 21 111 7552; E-mail: cimi@infarmed.pt; Linha do Medicamento: 800 222 444

Foi detetado, no mercado europeu, um certificado CE de conformidade falso (ver anexo) relativo a dispositivos médicos para diagnóstico *in vitro* pertencentes à lista B do anexo II do fabricante **DB Biotech, Inc.**.

O certificado falso faz referência ao organismo notificado Lloyd's Register Quality Assurance (0088), apresenta o número LRQ 5010189/A e validade de 21-02-2019 a 10-08-2019.

Esta falsificação foi identificada pelo organismo notificado.

Em Portugal não foram identificados registos ativos da comercialização de dispositivos médicos deste fabricante, mas, atendendo a que existe livre circulação de produtos no espaço económico europeu, o Infarmed recomenda que os produtos identificados no certificado não sejam adquiridos nem utilizados, uma vez que apresentam aposta marcação CE 0088 falsa.

A existência destes dispositivos em Portugal deve ser reportada à Direção de Produtos de Saúde do Infarmed através dos contactos: tel.: +351 21 798 72 35; e-mail: daps@infarmed.pt.

O Conselho Diretivo

Maria Sofia Rodrigues Pintado de Oliveira Martins

Assinado de forma digital por Maria Sofia Rodrigues Pintado de Oliveira Martins
Dados: 2019.05.30 13:07:52 +01'00'

INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
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Anexo – Certificado CE de conformidade falso

Lloyd's Register

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

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:

DB Biotech, Inc.
Popradska 80,
040 11 Kosice,
Solvak Republic

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. In addition for List A products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule and continued satisfactory compliance with the requirements for verification of manufactured product.

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 5010189/A
Original Approval:	21 February 2005
Current Certificate:	21 February 2019
Certificate Expiry:	10 August 2019

LRQA Notified Body Number 0088

David Dennis

Issued by: Lloyd's Register Quality Assurance Limited

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Lloyd's Register

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 4001276/A 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:

DB Biotech, Inc
Popradska 80,
040 11 Kosice,
Solvak Republic

Annex II List B Products

IHC-P APPLICATION

S12-I
K13-A
M26-A
A25-G
A21-Y
H16-E
K22-Y
E17-P
E19-G
K20-T
P16-D
G22-L
P14-V
A19-P
R17-S
S21-V
D28-E
G27-P
P21-S
D24-G
S20-D
R21-V

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DB Biotech, Inc
Popradska 80,
040 11 Kosice,
Solvak Republic

Annex II List B Products

IHC-P APPLICATION

E16-I
C16-I
L21-A
N26-R
P17-V
G21-G
A20-E
A24-V
T16-K
R15-K
D19-N
R20-S
V21-R
R20-H
E16-L
E28-P
A24-T
X22-C
A21-W
E18-E
C21-Q

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Popradska 80,
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Solvak Republic

Annex II List B Products

IHC-P APPLICATION

N29-D
E19-I
I27-I
E28-S
M16-L
E18-V
Q19-E
R19-D
Q21-Q
D25-R
N28-A
G11-G
E20-V
I17-T
E17-L
Q17-L
E26-A
Q22-S
E20-I
V22-E
Y19-I

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DB Biotech, Inc
Popradska 80,
040 11 Kosice,
Solvak Republic

Annex II List B Products

FITC APPLICATION

D22-G
N20-N
Q19-V
K21-L
R20-F
I27-K
S19-V
N25-P
T22-A
P21-P
H21-E
Q20-K
E20-D
H17-A
S25-H
H22-E
K16-P
N21-G
Y14-H
S7-R

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DB Biotech, Inc
Popradska 80,
040 11 Kosice,
Solvak Republic

Annex II List B Products

FITC APPLICATION

A17-A
I15-E
P12-E
Q11-T
R12-L
K17-H
H15-S
K21-F
L14-A
I15-P
V19-T
D17-G
D13-E
FITC Rabbit IgG - Isotype control

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DB Biotech, Inc
Popradska 80,
040 11 Kosice,
Solvak Republic

Annex II List B Products

DETECTION SYSTEM

DB Detection KIT-HRP/DAB
DB Detection KIT-HRP/DAB
DB Detection system-HRP
DB Primary Antibody diluent
DB Primary Antibody diluent
DB Antigen retrieval solution
DB Antigen retrieval solution
DB Antigen retrieval solution
DB Antigen retrieval solution

Schedule Issue: 02

Date of Schedule Issue: 21 February 2019

LRQA Notified Body Number 0088

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