

Circular Informativa

N.º 129/CD/8.1.7.

Data: 07/07/2015

Assunto: **Certificado CE de conformidade falso – Fabricante OMC Healthcare (Pvt.) Ltd.**

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 detetada, no mercado europeu, a existência de um certificado CE de conformidade falso relativo a dispositivos médicos de diagnóstico *in vitro* do fabricante **OMC Healthcare (Pvt.) Ltd.**

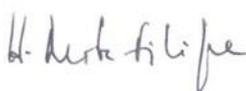
O certificado falso apresenta o número 10674 2 e referência à entidade CVI, s.r.o., que não se encontra designada para a Diretiva 98/79/CE relativa a dispositivos médicos de diagnóstico *in vitro*.

O certificado falso indica que o mesmo é válido de 17/11/2013 a 17/11/2018. Este certificado é relativo a **kits de testes de diagnóstico *in vitro* de doenças infecciosas, hormonas de fertilidade, marcadores tumorais, marcadores cardíacos, análise de urina e testes rápidos de doenças entéricas & abuso de drogas**, conforme anexo.

Em Portugal, não foi verificada a existência de registo da comercialização de dispositivos médicos deste fabricante mas, atendendo a que existe livre circulação de produtos no espaço económico europeu, o Infarmed recomenda que:

- Caso seja detetada a existência de dispositivos médicos de diagnóstico *in vitro* do fabricante **OMC Healthcare (Pvt.) Ltd.**, associados ao certificado supramencionado, estes não sejam adquiridos e utilizados, uma vez que não foram alvo de avaliação de conformidade e ostentam marcação CE falsa, o que põe em causa a sua segurança, qualidade e desempenho;
- A existência destes dispositivos em Portugal seja reportada à Direção de Produtos de Saúde do Infarmed através dos contactos: tel.: +351 21 798 72 35; fax: +351 21 798 72 81; e-mail: daps@infarmed.pt.

O Conselho Diretivo



Helder Mota Filipe
Vice-Presidente
do Conselho Diretivo

Anexo





Annexure 1 to Certificate No. 10674 2
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Device Name	Type/ Model / Ref No
Test for Infectious Diseases	
HBsAg (Hepatitis B Virus surface Antigen), 100 Strips/Box, Serum/Plasma	Q02-01-41
HBsAg (Hepatitis B Virus surface Antigen), 40 Cassettes/Box, Serum/Plasma	Q02-01-42
HBsAg (Hepatitis B Virus surface Antigen), 100 Strips/Box, Serum/Plasma	Q02-01a-41
HBsAb (Hepatitis B Virus surface Antibody), 100 Strips/Box, Serum/Plasma	Q02-01a-42
HBsAb (Hepatitis B Virus surface Antibody), 40 Cassettes/Box, Serum/Plasma	Q02-01b-41
HBsAb (Hepatitis B Virus surface Antibody), 100 Strips/Box, Serum/Plasma	Q02-01b-42
HBcAg (Hepatitis B Virus e Antigen), 40 Cassettes/Box, Serum/Plasma	Q02-01c-41
HBcAb (Hepatitis B Virus e Antibody), 100 Strips/Box, Serum/Plasma	Q02-01c-42
HBcAb (Hepatitis B Virus e Antibody), 40 Cassettes/Box, Serum/Plasma	Q02-01d-41
HBcAb (Hepatitis B Virus core Antibody), 100 Strips/Box, Serum/Plasma	Q02-01d-42
HBcAb (Hepatitis B Virus core Antibody), 40 Cassettes/Box, Serum/Plasma	Q02-01e-41
pre S1 (Pre-S1 Antigen of Hepatitis B Virus), 100 Strips/Box, Serum/Plasma	Q02-01e-42
pre S1 (Pre-S1 Antigen of Hepatitis B Virus), 40 Cassettes/Box, Serum/Plasma	Q02-02-41
HCV (Hepatitis C Virus Antibody), 100 Strips / Box, Serum/Plasma	Q02-02-42
HCV (Hepatitis C Virus Antibody), 40 Cassettes/Box, Serum/Plasma	Q02-03-41
HIV (Human Immunodeficiency Virus 1/2 Antibody), 100 Strips/Box, Serum/Plasma	Q02-03-42
HIV (Human Immunodeficiency Virus 1/2 Antibody), 40 Cassettes/Box, Serum/Plasma	Q02-04-41
TP (Treponema Pallidum Antibody), 100 Strips/Box, Serum/Plasma	Q02-04-42
TP (Treponema Pallidum Antibody), 40 Cassettes/Box, Serum/Plasma	Q02-05-41
HP (Helicobacter Pylori Antibody), 100 Strips/Box, Serum/Plasma	Q02-05-42
HP (Helicobacter Pylori Antibody), 40 Cassettes/Box, Serum/Plasma	Q03-01-31
Mal p/fpv (Malaria p/fpv Antigen), 100 Strips/Box, Whole Blood	Q03-01-32
Mal p/fpv (Malaria p/fpv Antigen), 40 Cassettes/Box, Whole Blood	Q03-01a-31
Mal p/fpan (Malaria p/fpan Antigen), 100 Strips/Box, Whole Blood	Q03-01a-32
Mal p/fpan (Malaria p/fpan Antigen), 40 Cassettes/Box, Whole Blood	Q03-02-21
DenNS1 (Dengue NS1 Antigen), 100 Strips/Box, Serum or WB	Q03-02-22
DenNS1 (Dengue NS1 Antigen), 40 Cassettes/Box, Serum or WB	Q03-02a-41
Den IgG/IgM (Dengue IgG/IgM Antibody), 100 Strips/Box, Serum/Plasma or WB	Q03-02a-42
Den IgG/IgM (Dengue IgG/IgM Antibody), 40 Cassettes/Box, Serum/Plasma or WB	Q03-03-61
VCO139 (Vibrio Cholerae O139), 100 Strips/Box, Others	Q03-03-62
VCO139 (Vibrio Cholerae O139), 40 Cassettes/Box, Others	Q03-03a-61
VCO1-O (Vibrio Cholerae O1 Serotype Ogawa), 100 Strips/Box, Others	Q03-03a-62
VCO1-O (Vibrio Cholerae O1 Serotype Ogawa), 40 Cassettes/Box, Others	Q03-03b-61
VCO1-I (Vibrio Cholerae O1 Serotype Inaba), 100 Strips/Box, Others	Q03-03b-62
VCO1-I (Vibrio Cholerae O1 Serotype Inaba), 40 Cassettes/Box, Others	Q03-06-41
Scrub Typhus (Scrub Typhus IgG Antibody), 100 Strips/Box, Serum/Plasma	Q03-06-42
Scrub Typhus (Scrub Typhus IgM Antibody), 40 Cassettes/Box, Serum/Plasma	Q03-06a-41
Scrub Typhus (Scrub Typhus IgM Antibody), 100 Strips/Box, Serum/Plasma	Q03-06a-42
Scrub Typhus (Scrub Typhus IgM Antibody), 40 Cassettes/Box, Serum/Plasma	Q03-07-41
Kalazar (V. Leishmaniasis test), 40 Cassettes/Box, Serum/Plasma	Q03-07-42
Kalazar (V. Leishmaniasis test), 100 Strips/Box, Serum/Plasma	Q03-04-42
Infectious Combo (HBsAg, HCV & HIV), 40 Cassettes/box, Serum/Plasma	Q03-05-62
VCO combo (VCO139, VCO1-O & VCO1-I), 40 Cassettes/box, Others	
Rapid Test for Tumor Markers	
CEA (Carcinoembryonic Antigen), 100 Strips/Box, Serum/Plasma	Q04-01-41
CEA (Carcinoembryonic Antigen), 40 Cassettes/Box, Serum/Plasma	Q04-01-42
FOB (Fecal Occult Blood), 100 Strips/Box, Fecal Extract	Q04-02-61
FOB (Fecal Occult Blood), 40 Cassettes/Box, Fecal Extract	Q04-02-62
AFP (Alpha - Fetoprotein), 100 Strips/Box, Serum/Plasma	Q04-03-41
AFP (Alpha - Fetoprotein), 40 Cassettes/Box, Serum/Plasma	Q04-03-42
PSA (Prostate Specific Antigen), 100 Strips/Box, Serum/Plasma	Q04-04-41
PSA (Prostate Specific Antigen), 40 Cassettes/Box, Serum/Plasma	Q04-04-42
CA125 (Cancer- Associated Antigen), 100 Strips/Box, Serum/Plasma	Q04-05-41
CA125 (Cancer- Associated Antigen), 40 Cassettes/Box, Serum/Plasma	Q04-05-42
Test for Cardiac Markers	
troponin I (Troponin I), 100 Strips/Box, Serum/Plasma	Q05-01-41
troponin I (Troponin I), 40 Cassettes/Box, Serum/Plasma	Q05-01-42
troponin T (Troponin T), 100 Strips/Box, Serum/Plasma	Q05-02-41
troponin T (Troponin T), 40 Cassettes/Box, Serum/Plasma	Q05-02-42
CK-MB (Creatine Kinase Isoenzymes), 100 Strips/Box, Serum/Plasma	Q05-03-41
CK-MB (Creatine Kinase Isoenzymes), 40 Cassettes/Box, Serum/Plasma	Q05-03-42
myoglobin, 100 Strips/Box, Serum/Plasma	Q05-04-41
myoglobin, 40 Cassettes/Box, Serum/Plasma	Q05-04-42
B-type Natriuretic Protein, 100 Strips/Box, Serum/Plasma	Q05-05-41
B-type Natriuretic Protein, 40 Cassettes/Box, Serum/Plasma	Q05-05-42
troponin I (Troponin I), 100 Strips/Box, Serum/Plasma	Q05-06-41
troponin I (Troponin I), 40 Cassettes/Box, Serum/Plasma	Q05-06-42
troponin T (Troponin T), 100 Strips/Box, Serum/Plasma	Q05-07-32
troponin T (Troponin T), 40 Cassettes/Box, Whole Blood	



Jan Gasper
director

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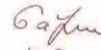
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Annexure 1 to Certificate No. 10674 2
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Device Name	Type/ Model / Ref.No
pid Test for Drug of Abuse	
AMP (Amphetamine), 100 Strips/Box, Urine	Q06-01-11
AMP (Amphetamine), 40 Cassettes/Box, Urine	Q06-01-12
BAR (Barbiturates), 100 Strips/Box, Urine	Q06-02-11
BAR (Barbiturates), 40 Cassettes/Box, Urine	Q06-02-12
BZO (Benzodiazepine), 100 Strips/Box, Urine	Q06-03-11
BZO (Benzodiazepine), 40 Cassettes/Box, Urine	Q06-03-12
COC (Cocaine), 100 Strips/Box, Urine	Q06-04-11
COC (Cocaine), 40 Cassettes/Box, Urine	Q06-04-12
B-COC (Benzoylcegonine), 100 Strips/Box, Urine	Q06-05-11
B-COC (Benzoylcegonine), 40 Cassettes/Box, Urine	Q06-05-12
MDMA (Methylenedioxyamphetamine), 100 Strips/Box, Urine	Q06-06-11
MDMA (Methylenedioxyamphetamine), 40 Cassettes/Box, Urine	Q06-06-12
MET (Methamphetamine), 100 Strips/Box, Urine	Q06-07-11
MET (Methamphetamine), 40 Cassettes/Box, Urine	Q06-07-12
MOR (Morphine), 100 Strips/Box, Urine	Q06-08-11
MOR (Morphine), 40 Cassettes/Box, Urine	Q06-08-12
OPI (Opiates), 100 Strips/Box, Urine	Q06-09-11
OPI (Opiates), 40 Cassettes/Box, Urine	Q06-09-12
MTD (Methadone), 100 Strips/Box, Urine	Q06-10-11
MTD (Methadone), 40 Cassettes/Box, Urine	Q06-10-12
TCA (Tricyclic Antidepressants), 100 Strips/Box, Urine	Q06-11-11
TCA (Tricyclic Antidepressants), 40 Cassettes/Box, Urine	Q06-11-12
THC (Tetrahydrocannabinol), 100 Strips/Box, Urine	Q06-12-11
THC (Tetrahydrocannabinol), 40 Cassettes/Box, Urine	Q06-12-12
BUP (Buprenorphine), 100 Strips/Box, Urine	Q06-13-11
BUP (Buprenorphine), 40 Cassettes/Box, Urine	Q06-13-12
Multi-Drugs Test - 2 Panel, 40 Cassettes/Box, Urine	Q06-14-12
Multi-Drugs Test - 3 Panel, 40 Cassettes/Box, Urine	Q06-15-12
Multi-Drugs Test - 4 Panel, 40 Cassettes/Box, Urine	Q06-16-12
Multi-Drugs Test - 5 Panel, 40 Cassettes/Box, Urine	Q06-17-12
Multi-Drugs Test - 6 Panel, 40 Cassettes/Box, Urine	Q06-18-12
Multi-Drugs Test - 7 Panel, 40 Cassettes/Box, Urine	Q06-19-12
Multi-Drugs Test - 8 Panel, 40 Cassettes/Box, Urine	Q06-20-12
Multi-Drugs Test - 9 Panel, 40 Cassettes/Box, Urine	Q06-21-12
Multi-Drugs Test - 10 Panel, 40 Cassettes/Box, Urine	Q06-22-12

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Jan Gasper
Director



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d Test for Fertility		
hCG S/U (hCG Serum/Urine Combo), 100 Strips/Box, Serum/Urine		Q01-01-51
hCG S/U (hCG Serum/Urine Combo), 40 Cassettes/Box, Serum/Urine		Q01-01-52
hCG (Human Chorionic Gonadotropin), 100 Strips/Box, Urine		Q01-01a-11
hCG (Human Chorionic Gonadotropin), 40 Cassettes/Box, Urine		Q01-01a-12
hCG (hCG Ultra Sensitive Early Detection), 100 Strips/Box, Urine		Q01-01a-13
hCG (hCG Ultra Sensitive Early Detection), 40 Cassettes/Box, Urine		Q01-01b-11
hCG (hCG Ultra Sensitive Early Detection), 01 Midstream/Box, Urine		Q01-01b-12
LH (Luteinizing Hormone), 100 Strips/Box, Urine		Q01-01b-13
LH (Luteinizing Hormone), 40 Cassettes/Box, Urine		Q01-02-11
LH (Luteinizing Hormone), 1 Midstream/Box, Urine		Q01-02-12
FSH (Follicle Stimulating Hormone), 100 Strips/Box, Urine		Q01-02-13
FSH (Follicle Stimulating Hormone), 40 Cassettes/Box, Urine		Q01-03-11
FSH (Follicle Stimulating Hormone), 1 Midstream/Box, Urine		Q01-03-12
FSH (Follicle Stimulating Hormone), 1 Midstream/Box, Urine		Q01-03-13
Urine Analysis Strips		
Glucose, 100 strips/bottle, Urine		Q09-01-11b
Glucose/Ketone, 100 strips/bottle, Urine		Q09-02-11b
Glucose/Ketone/pH, 100 strips/bottle, Urine		Q09-03-11b
Glucose/Ketone/pH/Blood, 100 strips/bottle, Urine		Q09-04-11b
Glucose/Ketone/pH/Blood/Protein, 100 strips/bottle, Urine		Q09-05-11b
Glucose/Ketone/pH/Blood/Pro/Bili, 100 strips/bottle, Urine		Q09-06-11b
Glucose/Ketone/pH/Blood/Pro/Bili/Urobil, 100 strips/bottle, Urine		Q09-07-11b
Glucose/Ketone/pH/Blood/Pro/Bili/Urobil/Nit, 100 strips/bottle, Urine		Q09-08-11b
Glucose/Ketone/pH/Blood/Pro/Bili/Urobil/S. Gravity/Nit, 100 strips/bottle, Urine		Q09-09-11b
Glucose/Ketone/pH/Blood/Pro/Bili/Urobil/S. Gravity/Nit/Leukocyte,s 100 strips/bottle, Urine		Q09-10-11b
Glucose, 1strip/Box, Urine		Q09-01-11
Nitrite (UTI), 1strip/ Box, Urine		Q09-11-11
5-Parameters, 1strip/ Box, Urine		Q09-05-11
10-Parameters, 1strip/ Box, Urine		Q09-10-11
Enteric tests		
Adenovirus,, 100 strips/ Box, Others		Q08-01-61
Adenovirus 40 and 41, 100 strips/ Box, Others		Q08-01a-61
Clostridium difficile, 100 strips/ Box, Others		Q08-02-61
Cryptosporidium, 100 strips/ Box, Others		Q08-03-61
Cryptosporidium & Giardia, 100 strips/ Box, Others		Q08-03a-61
Escherichia coli O157, 100 strips/ Box, Others		Q08-04-61
Rotavirus, 100 strips/ Box, Others		Q08-05-61
Rotavirus & Adenovirus, 100 strips/ Box, Others		Q08-05a-61
Rotavirus & Adenovirus 40 and 41, 100 strips/ Box, Others		Q08-05b-61

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