WETENSCHAPPELIJK INSTITUUT
VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE
DE SANTÉ PUBLIQUE

Multiplicom
Ter attentie van Mevr. M. Goergen
Galileïlaan 18
B–2845 Niel

Quality of medical laboratories

Date: 03/06/2016
your ref.:
our ref.: WIV/IVD/342-15
annex(es):

contact: Jeroen.Poels
tel.: + 32 2 642 53 94
fax: + 32 2 642 56 45
e-mail: jeroen.poels@wiv-isp.be
IVD@wiv-isp.be

SUBJECT: IVD Notification

Dear Mrs Goergen,

Please find enclosed the original notification form for the CE marked in vitro diagnostic medical devices, notified to the Belgian Competent Authority. This notification form is an acknowledgement of your declaration that the in vitro diagnostic medical devices, mentioned hereunder, fully comply with the Directive 98/79 of the European Parliament and of the Council. Be aware that it is an offence to place on the market non-complying devices bearing the CE marking. This form does not represent an accreditation or approval by the Belgian Competent Authority.

Please inform us of any changes (change of company information, change of address, significant change of product, change of certificate) and of the discontinuation of the product.

For the products listed hereunder, the Belgian Competent Authority for in vitro diagnostic medical devices has entered the data referred to in point (a), and if applicable point (b), of Article 12(1) of Directive 98/79/EC into Eudamed in accordance with the Annex to Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed).

Sincerely yours,

Dr. Jeroen Poels
IVD Competent Authority

Rue Juliette Wytsmanstraat 14
1050 Brussels | Belgium
T + 32 2 642 51 11 | F + 32 2 642 50 01
www.wiv-isp.be

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Re: notification of IVD products according to the directive 98/79

Competent Authority: BE/CA02

Manufacturer: Multiplicom, Galileïlaan 18, B-2845 Niel, Belgium

Date of registration: 13/10/2015, 25/01/2016, 28/04/2016

Type of IVD: Instruments/ reagents for professional use

IVD	GMDN code	Registration number
BRCA MASTR Dx (MR-2012.008 & MR-2012.040)	38442	BE-CA02-192-12
454 MID Dx kit 1-8 (ML-2008.192)	38442	BE-CA02-193-12
454 MID Dx kit 9-16 (ML-2116.192)	38442	BE-CA02-211-12
454 MID Dx kit 17-24 (ML-2124.192)	38442	BE-CA02-212-12
454 MID Dx kit 25-32 (ML-2032.192)	38442	BE-CA02-213-12
454 MID Dx kit 33-40 (ML-2040.192)	38442	BE-CA02-214-12
MID Dx 1-48 for Illumina MiSeq (ML-2204.240)	38442	BE-CA02-427-13
MID Dx 49-96 for Illumina MiSeq (ML-2205.240)	38442	BE-CA02-428-13
CFTR MASTR Dx (MR-2021.024 & MR-2021.048)	38442	BE-CA02-219-14
FMF MASTR Dx (MR-2071.024 & MR-2071.096)	59478	BE-CA02-220-14
srMID for Illumina NGS systems (1-48; 96 tests) (ML-2206.096)	38442	BE-CA02-342-15
srMID for Illumina NGS systems (49-96; 96 tests) (ML-2207.096)	38442	BE-CA02-343-15
Clarigo (MR-2500.096)	59947	BE-CA02-344-15
Clarigo Reporter	38442	BE-CA02-346-15
BRCA Tumor MASTR Plus Dx (MR-2015.024)	38442	BE-CA02-006-16
SOMATIC 1 MASTR Plus Dx (MR-2182.024)	38442	BE-CA02-050-16

This notification contains **1** page and replaces the certificate issued on **05/06/2015**.

Dr. Jeroen Poels
IVD Competent Authority

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