Certificate of CE-Registration

MDSS Medical Device Safety Service

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

PlexBio Co., Ltd.
6F-1, No.351 Yangguang St.
Neihu Dist
Taipei City 11491
TAIWAN

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated November 13, 2017

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2017-11-13

Joy Grimm
Senior Consultant - IVD
MDSS GmbH

Annex A: November 13, 2017
Manufacturer: PlexBio Co., Ltd.

Model or Reference or Catalog or UDI Number	Device Trade/Brand Name (Notified)	Medical Device Nomenclature (Notified)	Nomenclature Code (Notified)	Nomenclature Description (Notified)	Class. (Notified)	EC Certificate No. & Expiry (Notified)	Registration Number
82000	PlexBio HPV Genotyping Kit	EDMA	15 04 40 41	Human Papilloma Virus Genotyping - NA Reagents	"Other"	N/A	DE/CA09/0170/P12/IVD/006-02
82019	IntelliPlex HPV Genotyping 30 Kit	EDMA	15 04 40 41	Human Papilloma Virus Genotyping - NA Reagents	"Other"	N/A	DE/CA09/0170/P12/IVD/006-02
82017	IntelliPlex HPV bDNA Genotyping Kit	EDMA	15 04 40 41	Human Papilloma Virus Genotyping - NA Reagents	"Other"	N/A	DE/CA09/0170/P12/IVD/006-02
82018	IntelliPlex HPV Genotyping Kit	EDMA	15 04 40 41	Human Papilloma Virus Genotyping - NA Reagents	"Other"	N/A	DE/CA09/0170/P12/IVD/006-02
80000-2	PlexBio 100 Fluorescent Analyzer	EDMA	26 09 10 01	Others NA Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/P12/IVD/005-02
82003	IntelliPlex KRAS G12/13 Mutation Kit	EDMA	16 02 01 02 00	K-ras	"Other"	N/A	DE/CA09/0170/P12/IVD/004-01
82022	IntelliPlex KRAS Mutation Plus Kit	EDMA	16 02 01 02 00	K-ras	"Other"	N/A	DE/CA09/0170/P12/IVD/004-01
82004	IntelliPlex BRAF V600 Mutation Kit	EDMA	16 02 01 90 00	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/IVD/003-02
82006	IntelliPlex EGFR Mutation Kit	EDMA	16 02 01 90 00	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/IVD/003-02
82023	IntelliPlex ALK Rearrangement Kit	EDMA	16 02 01 90 00	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/IVD/003-02
82024	IntelliPlex ROS1 Rearrangement Kit	EDMA	16 02 01 90 00	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/IVD/003-02
82020	IntelliPlex NRAS Mutation Kit	EDMA	16 02 01 90 00	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/IVD/003-02

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Medical Device Safety Service

Annex A: November 13, 2017
Manufacturer: PlexBio Co., Ltd.

Model or Reference or Catalog or UDI Number	Device Trade/Brand Name (Notified)	Medical Device Nomenclature (Notified)	Nomenclature Code (Notified)	Nomenclature Description (Notified)	Class. (Notified)	EC Certificate No. & Expiry (Notified)	Registration Number
80029	PlexBio Calibration Kit	EDMA	11 50 02 90	Other specific controls	"Other"	N/A	DE/CA09/0170/P12/IVD/002
80017-2	PlexBio Wash Station	EDMA	26 03 09	Other Washers	"Other"	N/A	DE/CA09/0170/P12/IVD/001
80033	IntelliPlex 1000 πCode Processor	EDMA	29 01 10 01	Other Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/P12/IVD/007 -01
82025	IntelliPlex RET/NTRK1 Rearrangement Kit	EDMA	16 02 01 04	ret	"Other"	N/A	DE/CA09/0170/P12/IVD/008

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