



Certificate of CE-Registration

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 October 24, 2018

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.

2018-10-24

Elsa Villanueva-Möller

Elsa Villanueva-Möller
Director of Administration / Business Development
MDSS GmbH

**Annex A: October 24, 2018
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/JVD/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/JVD/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/JVD/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/JVD/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/JVD/005-02
82003	IntelliPlex KRAS G12/13 Mutation Kit	EDMA	16 02 01 02 00	K-ras	"Other"	N/A	DE/CA09/0170/P12/JVD/004-01
82022	IntelliPlex KRAS Mutation Plus Kit	EDMA	16 02 01 02 00	K-ras	"Other"	N/A	DE/CA09/0170/P12/JVD/004-01
82004	IntelliPlex BRAF V600 Mutation Kit	EDMA	16 02 01 90	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/JVD/003-03
82006	IntelliPlex EGFR Mutation Kit	EDMA	16 02 01 90	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/JVD/003-03
82023	IntelliPlex ALK Rearrangement Kit	EDMA	16 02 01 90	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/JVD/003-03

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82024	IntelliPlex ROS1 Rearrangement Kit	EDMA	16 02 01 90	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/IVD/003-03
82020	IntelliPlex NRAS Mutation Kit	EDMA	16 02 01 90	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/IVD/003-03
82021	IntelliPlex PIK3CA Mutation Kit	EDMA	16 02 01 90	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/IVD/003-03
82028	IntelliPlex Lung Cancer Panel	EDMA	16 02 01 90	Other Acquired Gene or Chromosome Alteration Tests	"Other"	N/A	DE/CA09/0170/P12/IVD/003-03
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