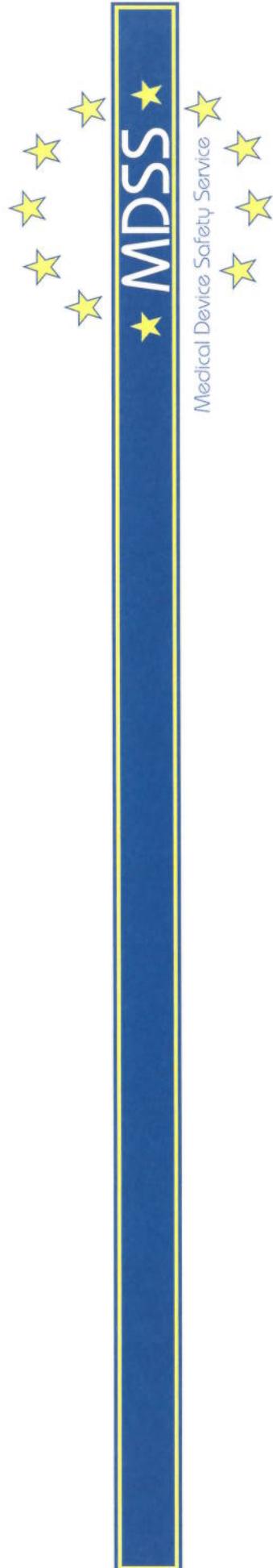


# Certificate of CE-Registration



This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC and the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

**Fjord Diagnostics Sdn. Bhd.  
49 Jalan Puteri 5/8, Puchong  
47100 Selangor  
MALAYSIA**

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 medical devices and has allocated registration numbers shown in:

**Annex A dated Aug 21, 2019**

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices and medical devices fulfill the applicable requirements of Directives 98/79/EC and 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2019-08-21

Dr. Philipp Hohenbrink  
Senior Consultant  
MDSS GmbH

**Annex A: Aug 21, 2019  
Manufacturer: Fjord Diagnostics Sdn Bhd**

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Notified Description	Class. (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
CY10-0PRO	CY-PREP® Liquid Based Cytology System - CY-100 Processor		EDMA	28 01 10 01	SP Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/F05/IVD/002
6888-0300	CY-PREP® Pap Test		EDMA	28 01 10 01	SP Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/F05/IVD/002
6886-0300	CY-PREP® Preservation Solution		EDMA	28 01 10 01	SP Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/F05/IVD/002
6887-0300	CY-PREP® Filter Slides Pack		EDMA	28 01 10 01	SP Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/F05/IVD/002
6881-2300	CY-PREP® Lysis Solution		EDMA	28 01 10 01	SP Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/F05/IVD/002
315A-0050	CY-PREP® /IHC-LINK® Microscope Slide		EDMA	28 01 10 01	SP Hardware + accessories + consumables + software	"Other"	N/A	DE/CA09/0170/F05/IVD/002
9801-0500	CERVIX-BRÚM® sampling device	individual pouch	UMDNS	22386	Sampling Kits, Endometrial	Class I	N/A	DE/CA09/0170/F05/002
9825-1000	CERVIX-BRÚM® sampling device	bulk pack	UMDNS	22386	Sampling Kits, Endometrial	Class I	N/A	DE/CA09/0170/F05/002
6801-0500	SPATULA+CYOBRUSH sampling devices	individual pouch	UMDNS	22386	Sampling Kits, Endometrial	Class I	N/A	DE/CA09/0170/F05/002
8801-1000	PAP SMEAR TESTPACK	Cervix-Brúm® +glass slide+slide mailer	UMDNS	22386	Sampling Kits, Endometrial	Class I	N/A	DE/CA09/0170/F05/002
8601-1000	PAP SMEAR TESTPACK	Spatula+CytoBrush +glass slide+slide mailer	UMDNS	22386	Sampling Kits, Endometrial	Class I	N/A	DE/CA09/0170/F05/002
PS01-0300	SEDIPREP® - PS 0.1		CND ver. 2018-03-13	W0599	IVD General Useable Devices - other <small>DISPOSITIVI IVD CONSUMABILI DI USO GENERALE - ALTRI</small>	"Other"	N/A	DE/CA09/0170/F05/IVD/003
PS02-0300	SEDIPREP® - PS 0.2		CND ver. 2018-03-13	W0599	IVD General Useable Devices - other <small>DISPOSITIVI IVD CONSUMABILI DI USO GENERALE - ALTRI</small>	"Other"	N/A	DE/CA09/0170/F05/IVD/003
PS04-0300	SEDIPREP® - PS 0.4		CND ver. 2018-03-13	W0599	IVD General Useable Devices - other <small>DISPOSITIVI IVD CONSUMABILI DI USO GENERALE - ALTRI</small>	"Other"	N/A	DE/CA09/0170/F05/IVD/003
PS06-0300	SEDIPREP® - PS 0.6		CND ver. 2018-03-13	W0599	IVD General Useable Devices - other <small>DISPOSITIVI IVD CONSUMABILI DI USO GENERALE - ALTRI</small>	"Other"	N/A	DE/CA09/0170/F05/IVD/003
PS08-0300	SEDIPREP® - PS 0.8		CND ver. 2018-03-13	W0599	IVD General Useable Devices - other <small>DISPOSITIVI IVD CONSUMABILI DI USO GENERALE - ALTRI</small>	"Other"	N/A	DE/CA09/0170/F05/IVD/003



## Manufacturer: Fjord Diagnostics Sdn Bhd

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Notified Description	Class. (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
PS10-0300	SEDIPREP® - PS 1.0		CND MKT. 2018-03-13	W0599	IVD General Useable Devices - other DISPOSITIVI INCONSUMABILI DI USO GENERALE - ALTRI	"Other"	N/A	DE/CA09/0170/F05/IVD/003
PS20-0300	SEDIPREP® - PS 2.0		CND MKT. 2018-03-13	W0599	IVD General Useable Devices - other DISPOSITIVI INCONSUMABILI DI USO GENERALE - ALTRI	"Other"	N/A	DE/CA09/0170/F05/IVD/003
PS30-0300	SEDIPREP® - PS 3.0		CND MKT. 2018-03-13	W0599	IVD General Useable Devices - other DISPOSITIVI INCONSUMABILI DI USO GENERALE - ALTRI	"Other"	N/A	DE/CA09/0170/F05/IVD/003
PS50-0300	SEDIPREP® - PS 5.0		CND MKT. 2018-03-13	W0599	IVD General Useable Devices - other DISPOSITIVI INCONSUMABILI DI USO GENERALE - ALTRI	"Other"	N/A	DE/CA09/0170/F05/IVD/003
PS80-0300	SEDIPREP® - PS 8.0		CND MKT. 2018-03-13	W0599	IVD General Useable Devices - other DISPOSITIVI INCONSUMABILI DI USO GENERALE - ALTRI	"Other"	N/A	DE/CA09/0170/F05/IVD/003
P100-0300	SEDIPREP® - PS 10		CND MKT. 2018-03-13	W0599	IVD General Useable Devices - other DISPOSITIVI INCONSUMABILI DI USO GENERALE - ALTRI	"Other"	N/A	DE/CA09/0170/F05/IVD/003
P120-0300	SEDIPREP® - PS 12		CND MKT. 2018-03-13	W0599	IVD General Useable Devices - other DISPOSITIVI INCONSUMABILI DI USO GENERALE - ALTRI	"Other"	N/A	DE/CA09/0170/F05/IVD/003
P140-0300	SEDIPREP® - PS 14		CND MKT. 2018-03-13	W0599	IVD General Useable Devices - other DISPOSITIVI INCONSUMABILI DI USO GENERALE - ALTRI	"Other"	N/A	DE/CA09/0170/F05/IVD/003

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