KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950
Telepon : (021) 5201590 Pesawat 2029, 8011
Faksimile : (021) 52964838 Kotak Pos : 203

GERMAS

Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

A L A T   K E S E H A T A N

KEMENKES RI AKL 20304127124

Nama Dagang / Merek	:	**BMS MIC IVD**
Kelompok / Kelas Resiko	:	Diagnostik *In Vitro* / C
Kategori Produk	:	Peralatan Imunologi dan Mikrobiologi
Sub Kategori	:	Perlengkapan dan Pereaksi Laboratorium Imunologi
Jenis Produk	:	RNA Preanalytical Systems.
Tipe / Ukuran	:	Mic IVD
Kemasan	:	Box, unit.
Nama Produsen / Pabrikan	:	BIO MOLECULAR SYSTEM, Australia Melalui BIOMED DIAGNOSTIC PTE. LTD, Singapore
Nama Pendaftar	:	PT. SINERGI INDOMITRA PRATAMA, DKI Jakarta
Atas dasar lisensi dari	:	-

Ketentuan

1. Persetujuan izin edar berlaku sampai dengan 29 Agustus 2023.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
4. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
5. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 19 November 2021

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LAMPIRAN

NOMOR IZIN EDAR
ALAT KESEHATAN
KEMENKES RI AKL 20304127124

No.	Deskripsi	Tipe / Kode
1	Power adaptor MIC-PA	
2	Tubes and caps MIC-TUBES	
3	Capping tool MIC-CT	
4	Myra loading block for Mic racks MYRA-LBMIC	

Dengan ketentuan bahwa izin edar tersebut hanya berlaku untuk deskripsi dan tipe / kode produk yang tercantum dalam lampiran ini

Jakarta, 19 November 2021

Ditandatangani Secara Elektronik Oleh :

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

a.n Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT

Ir. Sodikin Sadek, M.Kes
NIP.19621203 198603 1 004

micIVD Platform Specifications

Hardware

Thermal Performance	
Temperature Accuracy	±0.25°C
Temperature Uniformity	±0.1°C
Temperature Input Range	40 – 99°C

Optical Detection System	
Detectors	Photodiode
Sources	LED
Green Channel	Ex 465nm Em 510nm
Yellow Channel	Ex 540nm Em 570nm
Orange Channel	Ex 585nm Em 618nm
Red Channel	Ex 635nm Em 675nm

Reaction Tubes	
Samples per instrument	48
Reaction Volume Range	5 – 30µL

Operating Environment	
Ambient Temperature	18 – 30°C
Relative Humidity	20 – 80%

Physical	
Dimensions	150x150x130mm
Cover Panel Colour	BMS Red
Lid Insert Panel	Mic IVD

Software

micIVD software to be based on micPCR v2.10 public release software with the following changes:

Device Identification	
Unique Device ID	micIVD software is locked to work with micIVD device ID instruments only. micPCR RUO micPCR software will not detect micIVD devices

Branding	
Splash screen	micIVD specific
Software title	micVD vX.Y.Z (<User level>) where X.Y.Z is the version number and <User level> is the user permission level
About screen	micIVD specific
User manual	micIVD specific

Access Control	
Levels provided	4 levels • Technician • Analyst • Administrator • Maintenance
Maintenance	Only accessible for IVD distributors. Full control of software and in addition can • Can perform TVS temperature verification • Select by using special 'micIVD Maintenance' shortcut created by 'micIVD Maintenance' installer
Administrator	Full software control of software including • Creating and editing of assays and templates • Editing of run profiles • Editing of instrument properties and updating firmware • Cannot perform TVS temperature verification • Default user level if no micIVD Windows user groups defined
Analyst	All Technician permissions, and in addition • Can create and edit analyses and reports • Can view run and assay profiles
Technician	• Create runs from templates • Can edit sample information • Can start and abort runs • Can only view (not create or edit) analyses or reports • Cannot view run or assay profiles

Analysis Types	
Included	• Cycling

	• Melt • Absolute Quantification
Excluded	• High Resolution Melt • Identifier • Allelic Discrimination • Relative Quantification • Projects

File Handling	
Identity and protection	• All files include Unique ID to lock file to micIVD software • All files include digital signature to prevent unauthorised modifications
Assay File	• Created and edited in Administrator Mode • Includes thermal profile and reaction and analysis information. Added to runs to shared information. • Technician and Analyst Mode users can only add assays with matching thermal profiles to runs • In Administrator and Maintenance Mode assay thermal profile will be merged with existing run thermal profile when assay is added
Run Template File	• Created/controlled by Administrator Mode users for use by Technician and Analyst users to create runs • Installed to a fixed directory (refer 'Install Template' menu below) • Can include additional predefined data (e.g. controls, sample names, run information) • New thermal profile, or updates to existing thermal profile requires a new run template file to be installed by user (refer 'Install Template' menu below).
Install Template menu	In Technician and Analyst Modes a new menu item 'Install Template' will be added to the 'Help' menu to allow users to install updated templates provided by Administrator.
New Run	In Technician and Analyst Modes will automatically use installed template file. Prompt for selection if more than one template installed. In Administrator and Maintenance Modes will create an empty run.
New Run From Template	Hidden in Technician and Analyst Modes
New Assay	Hidden in Technician and Analyst Modes
New Project	Removed
Save as Template	Hidden in Technician and Analyst Modes
Template Filename Extension	micivdtemplate
Run Filename Extension	micivdrun
Assay Filename Extension	micivdassay

Assays	
Automatic Analysis Generation (per target)	Setting to automatically add analysis at conclusion of successful run. All data must be present (not aborted or failed) and not suspected of optical failure

Sample Setup	
Available assays	Assay list on sample editor shows all assays included in template file.
Sample Type Options	Unknown, Standard, PositiveControl, NegativeControl, NTC, NRT
Groups	Groups columns and setup area removed (only required for Relative Quantitation Analysis type)
Available columns	Colour, Name, Type, Assay, Standards Concentration, Input DNA Concentration, Input RNA Concentration, RIN, Comment
Removed columns	Groups, Multiplex Standards, Reference Material
Editing period	Sample setup cannot be changed after run starts in Technician or Analyst Mode

Analysis and Reporting	
Automatic report generation	A report will be automatically at the end of a completed run. The analysis report for each target will be listed in the report configuration panel. All standard report properties will be included.
Analysis parameters settings	Disabled (non editable) in Technician Mode
Analysis parameters save/load to assay	Hidden in Technician Mode Save to assay not hidden in Analysis Mode
Sample Selector	In Technician Mode cannot change sample selection but can hide/show samples. In Analyst, Administrator and Maintenance Mode can enable/disable samples, and hide/show samples.
Sample Selector Grouping	Remove group by 'Sample Group'

Temperature Verification System (TVS)	
Verification of Mic Temperature Sensor	Wizard driven system to verify Mic temperature accuracy.
Traceability	TVS calibration traceable to NATA reference standard.
Availability	Only available in Maintenance Mode

MIC IVD Labels Artwork

Mic IVD label is placed in the position on the carton as shown below:

MIC IVD Carton (39x39x26cm) (weighs 6kg).