

क्षेत्रीय आयुर्विज्ञान संस्थान, इंफाल: मणिपुर Phone : 0385-2414720 0385-2414720 0385-2414750 e-mail : nime@rima.edu.in (An Autonomous Institute under the Ministry of Health & Family Welfare, Govt. of India)

CALL FOR OBJECTION NOTICE

Subject: Purchase of Consumables for Bacterial Identification System(MALDI Biotyper Sirius One IVD system) for use in the Deptt. of Microbiology, RIMS, Imphal — inviting comments/objections thereon

This Institute is in the process for purchasing of Consumables for Bacterial Identification System (MALDI Biotyper Sirius One IVD system) for use in the Deptt. of Microbiology, RIMS, Imphal, on Proprietary nature from M/S BioInnovations, Thane, Mumbai, being authorised distributor of Bruker Daltonics India Pvt. Ltd. The proposal submitted by M/S BioInnovations, Mumbai and Proprietary Article Certificate (PAC) with relevant documents are enclosed.

- The above documents are being uploaded at RIMS website for an open invitations to all stakeholders to submit obligation/ objections, from the relevant manufacturers across India, regarding the proprietary and cost of nature of the consumables, within 10 days from the date of issue of this Notice, with reference to GEM Contract No.GEMC-511687759619287 dated 7th Feb., 2023 for purchase of Bacterial Identification System (MALDI Biotyper Sirius One IVD system) supplied by M/S Bioinnovations, Thane, Mumbai and manufactured by Bruker Daltonics India Pvt. Ltd.
- The comments should reach RIMS, Imphal, at official **E-mail**: rims.imphal@gov.in on or before 18th July, 2025 upto 4:00 P.M., failing which, it will be presumed that stakeholders have no objection to the Proprietary Nature of the consumables mentioned below:-

Sl. No.	Product Description	
1.	Bruker Matrix HCCA	
2.	Bacterial Test Standard (BTS)	
3.	Maldi Sepsityper Kit 50	
4.	Mbt Star - Carba Kit	
5.	Mbt Star — Cepa Kit	
6.	Maldi Target Plates	(4)

Encl: As stated above.

Signed by Mecolt Rajkumar Singh Date; 08-07-2025, 18:46:55 Deputy Director(Admn.)

Copy to: -

- 1. P.S. to the Director, RIMS, Imphal for kind information
- 2. The HOD, Microbiology, RIMS, Imphal
- 3. The CAO/FA, RIMS, Imphal
- 4. The System Administrator, RIMS, Imphal- for uploading the "Call for Objection" Notice with other relevant documents to RIMS website.
- 5. Guard File

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सक्ष्मजीवविज्ञान विभाग

DEPARTMENT OF MICROBIOLOGY

Phone

Website: www.rims.edu.in : 0385 - 2414629

0385 - 2414750

Ext : 241 (Office) 181 (HoD)

क्षेत्रीय आयुर्विज्ञान संस्थान, इंफाल: मणिपुर - ७९५००४ REGIONAL INSTITUTE OF MEDICAL SCIENCES, IMPHAL MANIPUR - 795004

(स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार के अंतर्गत एक स्वायत संस्थान)

(An Autonomous Institute under the Ministry of Health & Family Welfare, Govt. of India)

PROPRIETARY ARTICLE CERTIFICATE

(Procurement of the Goods under the provision of Rule 166 of GFR 2017-Procurement base on Single Tender Enquiry)

The indenter hereby certify that

- i. The indented goods/ software are manufactured / developed by
 - 1. Bruker Matrix HCCA manufactured by M/S Bruker India Scientific Pvt. Ltd.
 - 2. Bacterial Test Standard (BTS) manufactured by M/S Bruker India Scientific Pvt. Ltd
 - 3. Maldi Sepsityper Kit 50 manufactured by M/S Bruker India Scientific Pvt. Ltd
 - 4. Mbt star- Carba Kit manufactured by M/S Bruker India Scientific Pvt. Ltd.
 - 5. Mbt star- Cepa Kit manufactured by M/S Bruker India Scientific Pvt. Ltd.
 - 6. Maldi Target plates manufactured by M/S Bruker India Scientific Pvt. Ltd.

No other make or model / software is acceptable for the following reasons:ii.

The indented items are proprieting items ovailable in the open market.

iii. Supporting documents from supplier attached: Yes

(Dr Thongam Nabakumar Singh)

Professor & Store i/c Department of Microbiology, RIMS, Imphal.

> आचार्य / Professor सुक्ष्मजीव विज्ञान विभाग Department of Microbiology क्षेत्रीय आयुविज्ञान संस्थान, इम्फाल Regional Institute of Medical Sciences, Imphal

(Dr Heigrujam Rebachandra Si

Professor & Head Department of Microbiology, RIMS, Imphal.

Dr. Heigrujam Rebachandra Singh

डॉ: हैग्रजम रेबाचन्द्र सिंह

आचार्य एवं विभागाध्यक्ष / Professor & Head सक्ष्मजीव विज्ञान विभाग Department of Microbiology क्षेत्रीय आयुविज्ञान संस्थान, इम्फाल Regional Institute of Medical Sciences, Imphal

Requirements for the purchase of consumables and kits for MALDI-TOF

From: Shivam Pandey (shivam.pandey@bioinnovations.in)

To: drshakti_l@yahoo.co.in

Cc: microrims@gmail.com; dr_rebachandra@yahoo.com; mamta_ksh@yahoo.co.in; sales@bioinnovations.in;

asmita@bioinnovations.in; accounts@bioinnovations.in

Date: Wednesday 14 May, 2025 at 03:34 pm IST

Dear Dr. Shakti

Greetings from Bioinnovations!

As per our discussion regarding MALDI TOF consumables, please find the attached quotations of Bruker consumables and also attached PAC certificates and authorizations letter for your reference.

Please find the below clarifications of your questions.

1. Clarity on the system being a closed system or open system. Or a semi-closed system.

Ans. The quoted system is semi-closed system (As we have not mentioned anything in technical compliance during the tender, this point was not mentioned in tender technical compliance document)

2. If the reagents/kits are supplier/manufacturer specific, to provide Proprietary Certificate as per rule 166 of GFR 2017 along with supporting documents from supplier/manufacturer.

Ans. The PAC (Proprietary Article Certificate) for the Bruker product is attached. The remaining items (ACN, TFA, FA, Ethanol, etc.) can be sourced locally and are not manufacturer-specific.

3. To submit an approximate budget for a period of one year.

Ans. The quoted price is valid until 20th December 2025.

Kindly check these details and let me know if any clarifications is required.

Regards:

Shivam Pandey

Regional Sales Manager

Bioinnovations

Office no. 6&7, Darshana Heights, 1st floor,

Maheshwari Bhavan Road, Bhayander (w) Mumbai-401101

EST-BI2025-2026-010- RIMS.pdf 133.2kB



MBT consumables -Proprietary certificate.pdf 181.9kB



Athorization certificate Bruker.pdf

8452009336

Sshivam.pandey@bioinnovations.in Wwww.bioinnovations.in





These same standards apply fully to all of our suppliers, which we define as vendors, agents, distributors, lead finders, consultants and any subcontractors who may engage in support of Bruker's business across the globe. These standards also apply to all employees and agents of these suppliers. Bruker expects all Bruker's suppliers to conduct their business in a legally compliant manner. It is the responsibility of all Bruker suppliers to comply with the Bruker written Code of Business Conduct and policies as may be communicated to our suppliers in writing from time to time. Supplier shall not promote, market, include in a bid process, offer to sell or sell products under agreement with Bruker in violation of any applicable law or regulation issued by the European Union, the United States of America, the Territory or any other foreign government.

Should you have any questions, please feel free to contact Bruker accordingly.

Yours sincerely,

Bruker Daltonics GmbH & Co. KG,

represented by its General Partner Bruker Verwaltungs GmbH. the general Partner represented by

Doousioned by Yourn Goussy

Name: Yoann Gougay

Title:

APAC Commercial Director - M&ID

ppa. Guido Miss

Name: ppa. Guido Mix

Title:

BM&D / Sales



Bruker Daltonics GribH & Co. KG - Postfach 33 01 26 - 28331 Bromen

TO WHOM IT MAY CONCERN

Bruker Deltonics GmbH & Co. KG Fahrenheitstraße 4 28359 Bremen, Germany Tel: +49 (0)421-2205-0 Fax: +49 (0)421-2205-100 office-bdal@bruker.com

August 24, 2023

CERTIFICATE OF DISTRIBUTORSHIP

This document certifies that:

Bioinnovations
C-14, Waghani Mahal, Station Road
Bhayander West, Thane
Mumbai 401101
Maharashtra, India

Is an authorized DISTRIBUTOR (FN2021-1-30386) in India for Clinical Market and is fully authorized to submit bids and negotiate contract price, terms and conditions and execute sales contracts for the following Bruker Products:

MALDI Biotyper system and all related products according to Exhibit A1 of Distribution Agreement M&D

This Certificate of Distributorship is valid until March 31, 2026 or notification of withdrawal, whatever comes first, and is subject to be renewed.

Bruker's values and position on Ethics fully apply to this Certificate of Distributorship:

At Bruker, which includes Bruker Corporation and all of its direct and indirect subsidiaries, we value integrity, respect and trust. Ethical behavior and compliance are at the heart of our business. The words, "Innovation with Integrity" are a call to every one of us to pursue excellence in every aspect of our business. It is the cornerstone of everything we do and the basis of everything we stand for as a Company.

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Bankverbindung: Dendsche Bare AG Kome 204-264-900 - PL Z 200 701 80 ISAN 1 BESS 250 * USG 6204-7440 00 BU Frank 1941 FTD FERS XX



Bruker India Scientific Pvt. Ltd.

Unit No.609, 6th Floor, West Wing, Satellite Gazebo, Guru Hargovindji Marg, Andheri Ghatkopar Road, Andheri Eost, Mumbai - 400 093.

CIN No. U33100MH1985PTC035138
Tel. :+ 91 (22) 51126809 - 8611
Email :sales.bdal.in@bruker.com
service.bdal.in@bruker.com

Website : www.bruker.com

22nd June 2023

TO WHOMSOEVER IT MAY CONCERN

MALDI Biotyper® Reagents : Proprietary Nature.

We hereby confirm that the below mentioned accessories/ consumables/ reagents are used along with MALDI Biotyper® instrument for microbial ID are proprietary in nature in terms of one or more than one of the features mentioned here such as patented technology/ specifically designed to use with/ concentration used/ Pack size/ Purity/ number of calibrants/ nature of calibrant to do proper validation and calibration of the instrument/ to give accurate Identification of Microbe / for suitability of use.

P# 8270006 - Transporter box for MSP Biotarget

P# 8267615 – MSP adopter for Biotarget

P# 1840375 - MSP Biotarget 96

P# 8280800 - MSP 96 target Polished Steel

P# 8255344 – Bruker Matrix HCCA

P# 8255343 – Bruker Bacterial Test Standard (BTS)

For Bruker Daltonics India Private Ltd.,

G. Venkatesan

Senior Business Development Manager - MID



Bruker Daitonics GmbH & Co. kG - Postfach 93 61 26 - 28 231 Bramina

Bruker Daltonics GmbH & Co. KG Fahrenheitstraße 4 28359 Bremen, Germany Tel. +49 (0)421-2205-0 Fax +49 (0)421-2205-100 office-bdal@bruker.com www.bruker.com

Date: 31 August 2023

Customer Letter on Bruker Intellectual property

Dear Valued Bruker Customer!

We hereby inform you that the below-mentioned features of the instrument's hardware/ Software/ accessories/ Kits/ technology used are Bruker's proprietary in terms of patented technology or design or application for the quoted system package under the Registered name, MALDI Biotyper® system for microbial identification, Model: MALDI Biotyper® sirius or MALDI Biotyper® sirius one.

Please be aware that any promotion, distribution or end-user usage of the methods, software, kits described below, as the case may be, without a Bruker license may violate Bruker exclusive rights to that technology, i.e. patent, regardless if this is done directly by a company or via distributors.

Patent Title:

Mass spectrometric diagnosis of septicemia

Patent number:

EP2454377B1

Status:

granted (European Patent validated in: DE, FR, GB)

Patent number:

CN102471798 B

Status:

granted (China)

Related products:

MBT Sepsityper® IVD Kit, MBT HT Sepsityper IVD

module, MBT Compass IVD Sepsityper Module, MBT

Sepsityper Module.

Assignee:

Bruker Daltonics GmbH & Co. KG

Description: Protects the identification of microorganisms from positive blood cultures by mass spectrometry after isolation of the microorganisms with the Sepsityper method. For this, a strong tenside is used to destroy the blood cells, microorganisms are isolated by centrifugation or filtration.

Patent Title:

Mass spectrometric measurement of beta-lactamase

resistances

Patent number:

EP2580598B1

Status:

granted (European Patent validated in: DK, ES, FI, FR,

GB, IT, NO. SE, TR)

Patent number:

EP2806032B1



Status:

granted (European Patent validated in: DE, ES, FR, GB.

ĬT)

Patent number:

CN103003699 B

Status:

granted (China)

Related products:

MBT STAR-Cepha IVD kit, MBT STAR-Carba IVD kit,

MBT STAR-BL IVD module, MBT HT STAR-BL Module,

MBT HT STAR-BL IVD Module.

Assignee:

Bruker Daltonics GmbH & Co. KG

Description: Protects the detection of beta-lactamase activity by an in vitro-assay, incubation of beta-lactam antibiotic with bacteria, measurement of antibiotic/cleavage products by mass spectrometry. No kit claimed, but workflow/procedure.

Patent Title:

Methods and means for characterizing antibiotic

resistance in microorganisms

Patent number:

EP2606145B1

Status:

granted (European Patent validated in: AT, BE, BG, CH,

CZ, DE, DK, ES, FR, GB, GR, HR, HU, IE, IT, NL, NO,

PL, PT, RO, SE)

Patent number:

CN103108958 B) granted (China)

Status: Related products:

Related products: MBT STAR-Cepha IVD kit, MBT STAR-Carba IVD kit, MBT STAR-BL IVD module, MBT HT STAR-BL Module, MBT HT STAR-BL IVD

Module.

Licensee:

Bruker Daltonics GmbH & Co. KG (exclusively licensed

from Erasmus Medical Center, Rotterdam NL)

Description: Protects the detection of beta-lactamase activity by an in vitro assay, incubation of beta-lactam antibiotic with bacteria, measurement of antibiotic/cleavage products by mass spectrometry. Kit claimed and workflow/procedure (not identical but complementary to the Bruker patent, see above).

Patent Title:

Methods of detection

Patent number:

EP3589742 B1 (CN111094580 A)

Status:

granted (European Patent validated in: AT, BE, CH, CZ, DE, DK, ES, FR, GB, IE, IT, LU, MC, NL, NO, PL, SE;

application pending in China)

Related products:

MBT HT LipidART Module, MBT Lipid Xtract™ Kit

Licensee:

Bruker Daltonics GmbH & Co. KG (exclusively licensed

from Imperial College, London UK)

Description: Protects the detection of colistin resistance in bacteria by detection

of the modification of lipid A using MALDI-TOF MS.

Sincerely,

Your Bruker Team

Goann Gouge

Mr.Gougay Yoann

Commercial Director - APAC MID