Omark LIFESCIENCES

BUSINESS PROFILE

Omark LIFESCIENCES

QUALITY CONTROL

The growing fields of biotechnology and biomedical research such as gene therapy, molecular biology and DNA diagnostics, require a much more intense control of certified, contaminant-free, safe products. OMARK is proud to position itself as one of the few plastic manufacturers that completely fulfills all the requirements mentioned above and serves its wide variety of valuable customers in the best possible way

For sterile products, the initial microbiological tests are done for clean rooms.
The production can start only if the conditions of the clean rooms are valid. Also every batch of products is controlled with "Tryptic Soy Agar" at the end of an incubation period of 48 hours at 35-37°C and with "Saboround Dextrose Agar" at the end of an incubation period of 5 days at 22-25°C.

Only if these two controls pass the tests, then the products are taken outside the quarantine room.

Hence the process begins with inspection of the raw materials to monitoring the final product and ends with testing each lot after production for contaminants.

Omark Lifesciences is pleased to announce their New facility with injection moulding machines. With all equipment being at par with the current market requirements to ensure we are always using the latest technology and that which is the most suited to the many individual items we manufacture.

Our large investment in production innovation also sees an industry leading, highly automated plant. This can operate at full capacity 24 hours a day, seven days a week .

Such an automation focus provides considerable operational efficiencies and delivery guarantees.

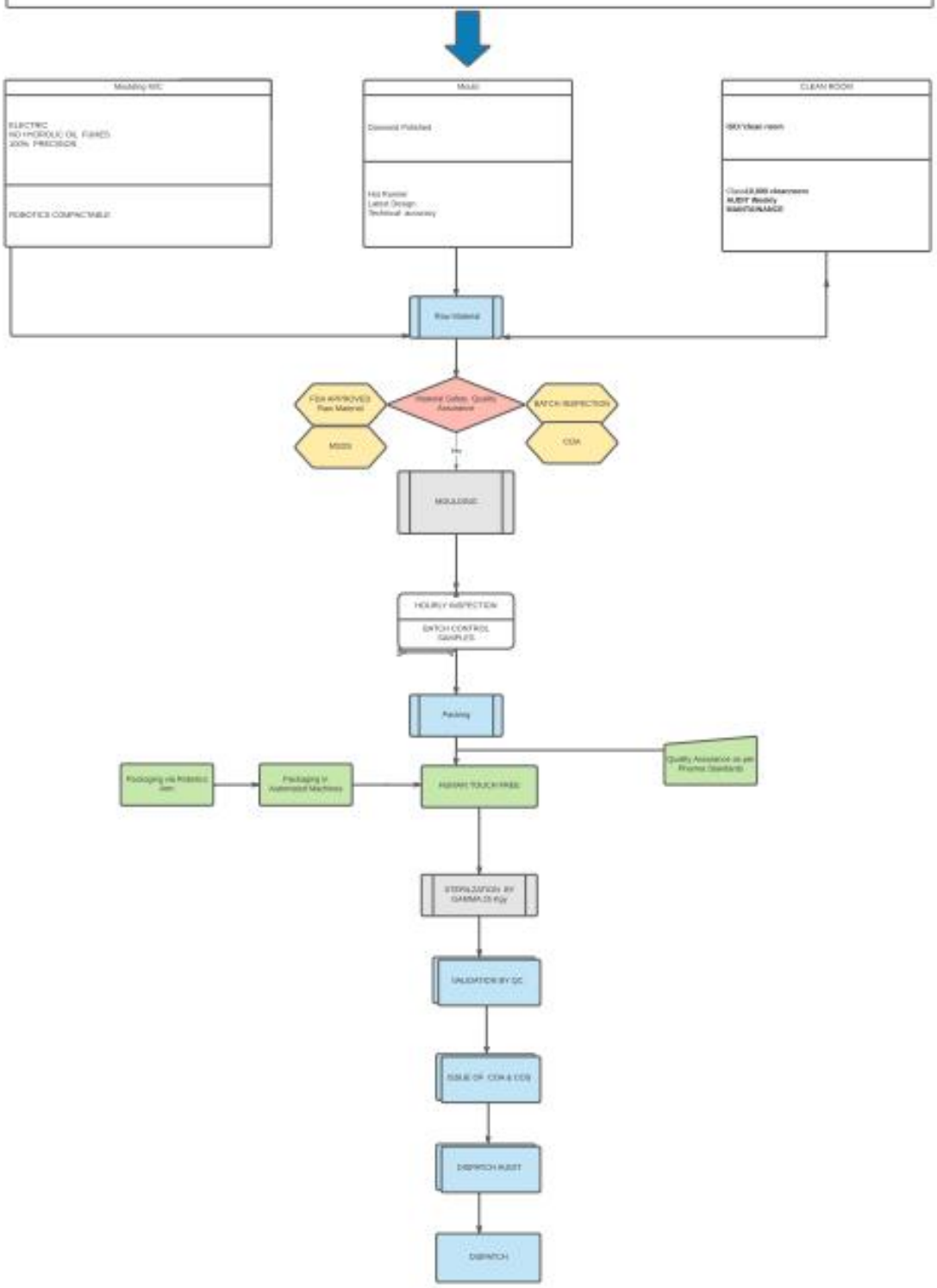
Most importantly, it helps deliver maximum product consistency and contributes to our uncompromising commitment to quality.

Our commitment is further enhanced by our unrelenting environmental controls which see all products being manufactured in a rigorously maintained 'clean environment'to produce DNAse, RNAse , and pyrogen free products.

Factors that play an important part is our ISO 9001:2015, CE & ISO 13485:2016

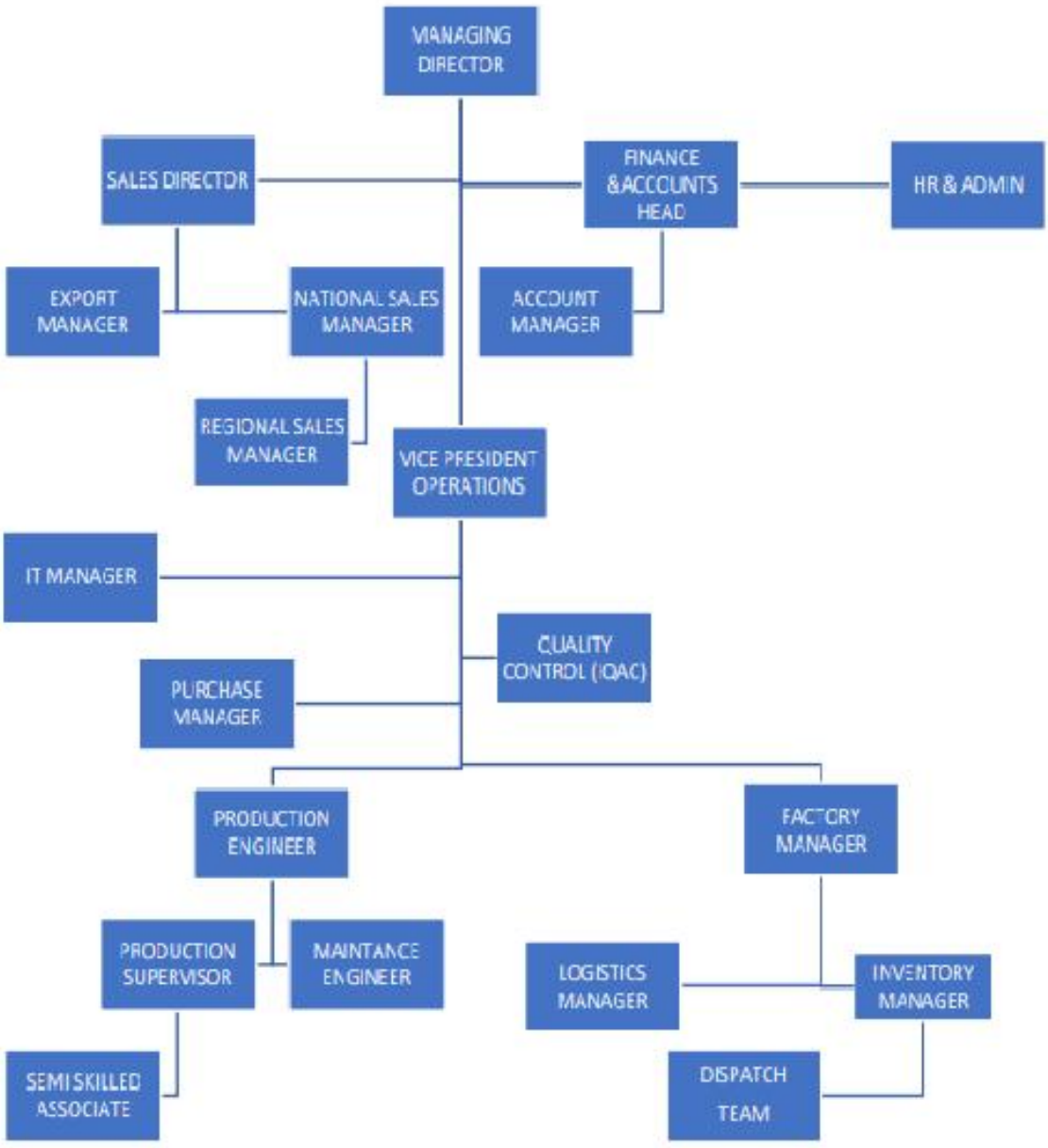
Alongside such manufacturing excellence are the standards we set and maintain to ensure our delivery responsiveness is second to none. So production and logistics are driven by advanced and fully integrated IT systems that are geared to maintaining optimum stock levels and then to picking and despatching ordered products quickly and fully accurately.

OMARK LIFESCIENCES PRODUCTION PROCESS



OMARK LIFESCIENCES PVT LTD

Plot Number 123, Toy CityEcotech-III Greater Noida, GB Nagar,
Uttar Pradesh-201306 ,India
GST : 09AADCO2970R1ZP




CE certification
ISO 9001: QMS
ISO 13485: For Medical devices – Quality management systems
ISO 11137: Gamma sterilization (Sterile R)
ISO 24988: Petri dish standards
ISO 8655: Accuracy Standards
ISO 6706: Accuracy Standards
DIN 12681: Accuracy Standards
Graduation Measurement Certification
Heavy Metal Certification
DNase RNase Free
ATP free
Endotoxin Free
Human DNA free

OMARK CERTIFICATIONS


WHY CHOOSE OMARK

We Resonate with Your Business

What's important to you and your business? Fast turnaround? Reliable supply chain? Flexible service? Collaboration and input from a trusted partner? That's all business as usual at Omark . But we also give you something else that's even more important: peace of mind that comes from working with a team that lives up to its word and keeps its promises.

We Specialize in the world of sterile disposable microbiological labware involving sterility systems, petridishes and Manufacture Medical Grade laboratory disposables as RIA VIALS /Test tubes

Customers Are Our Only Commitment.

Packaging

Raw materials are FDA approved

Technology Up-Gradation

Training Schedules

Quality Checks

QUALITY CONTROL

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FEATURES Omark Lifesciences Size 90*15 mm

- Manufactured either aseptically or gamma radiation sterilized under class 10,000 equivalent to iso class 7 clean room conditions.

- Perfect flatness to ensure the media's constant depth.

- Dishes are manufactured using crystal clear, virgin, high molecular medical grade polystyrene.

- Total clarity due to the location of the injection point situated on the side of the dish - bottom of the dish optimizes reading even by most advance image analyzing systems.

- The stacking ring is specially designed to improve the stacking of Dishes and making them more practical to use.

- Vent design for easy air exchange – triple vented.
- With the help of product label on each box, we can retrace each production cycle.
- High strength carton guarantees the transportation safety.
- The quality of the polystyrene used provides Dishes with a high level of mechanical resistance.

UKcert
Certification & Inspection

Certificate of Registration

This is to certify that the

Quality Management System

of

OMARK LIFESCIENCES PVT. LTD.

at

REGISTERED OFFICE:- A/38, SECTOR 12, NOIDA -201301, UTTAR PRADESH -201301, INDIA FACTORY:- PLOT NUMBER 123, TOY CITY ECOTECH-III GREATER NOIDA, GB NAGAR, UTTAR PRADESH-201306, INDIA

has been independently assessed and is compliant with the requirements of:

ISO 9001:2015

For the following scope of activities:

Manufacturing, Marketing and Global Supply of Plastic laboratory Consumables for Research use in Pharmaceutical, Diagnostics, Clinical Research and Other Life Sciences laboratories

Certificate Number: UQ - 2021020515

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	5th February 2021
1st Surveillance Audit Due	4th February 2022
2nd Surveillance Audit Due	4th February 2023
Certificate Expiry	4th February 2024

Authorised Signatory

ABSTRACT

ISO 9001:2015 specifies requirements for a quality management system :

- OMARK demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.
- OMARK aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

ISO 9001

Quality Management System

Certification & Inspection

Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirements Medical Devices 93/42/EEC as Amended 2007/47/EC

Certificate No.: CE-12020

Manufacturer

Name : OMARK LIFESCIENCES PVT. LTD.

Address : REGISTERED OFFICE- A/38, Sector 12, Noida -201301, Uttar Pradesh -201301, India
FACTORY- Plot Number 123, Toy City Ecotech III Greater Noida, GB Nagar, Uttar Pradesh-201306, India

Product : Plastic laboratory Consumables for Research use in Pharmaceutical, Diagnostics, Clinical Research and Other Life Sciences laboratories

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Medical Devices 93/42/EEC as Amended 2007/47/EC

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant Standard testing performance, the manufacturer shall affix to each device, of the referenced models.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one example of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	05th February 2021
1st Surveillance Audit Due	04th February 2022
2nd Surveillance Audit Due	04th February 2023
Certificate Expiry (subject to the company maintaining its system to the required standard)	04th February 2024

Authorised Signatory

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website: www.ukcertifications.org.uk, email: info@ukcertifications.org.uk
Company No. 11447851

ABSTRACT

- OMARK is authorized CE on its products **in trade movement in the European Economic Area.**
- **OMARK Conformity with Europe**, demonstrate that the products have been audited/assessed in terms of minimum safety, health and environmental requirements.
- OMARK CE marking also indicates fair competition among manufacturers as it enforces accountability and conformity with the same requirements

CE: Certificate of Compliance

ISO 13485 : Quality Management System

UKcert
Certification & Inspection

Certificate of Registration

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Quality Management System for Medical Devices
of

OMARK LIFESCIENCES PVT. LTD.

at

REGISTERED OFFICE:- A/38, SECTOR 12, NOIDA -201301, UTTAR PRADESH -201301, INDIA FACTORY:- PLOT NUMBER 123, TOY CITY ECOTECH-III GREATER NOIDA, GB NAGAR, UTTAR PRADESH-201306, INDIA

has been independently assessed and is
compliant with the requirements of:

ISO 13485:2016

For the following scope of activities:

Manufacturing, Marketing and Global Supply of Plastic laboratory Consumables for Research use in Pharmaceutical, Diagnostics, Clinical Research and Other Life Sciences laboratories

Certificate Number: UQ-2021020516

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	5th February 2021
1st Surveillance Audit Due	4th February 2022
2nd Surveillance Audit Due	4th February 2023
Certificate Expiry	4th February 2024

Authorised Signatory

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71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11447831

ABSTRACT

A) OMARK accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

B) OMARK is committed in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support).

• ISO 13485:2016 specifies requirements for a quality management system , OMARK demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

C) OMARK is committed to empower 5 clauses of ISO 13485 that are numbered 4, 5, 6, 7, 8

4 . Quality management system
5 . Management responsibility
6 . Resource management
7 . Product /service realization
8 . Measurement, analysis and improvement

TECHNICAL DATA SHEET

Omark Lifesciences Pvt. Ltd.

Plastic Petridish for Cat. No. : OMK-PD9015

Specification

1.1 Description: **Petri Dish- Gama Radiated Sterile**
1.2 Design: **Shallow dish design**

1.3 Specifications:

Transparent, disposable round plates with excellent optical clarity and strength. Petri plate recommended for laboratory use. For in-vitro use only.

Application : Bioassays ,Antimicrobial susceptibility tests , General lab purposes and Observation of plant germination

Code	Ø x h (mm)	Material	No. Per Case
OMK-PD9015	90X15	PS	480

1.4. Performance Specifications:

1.4.1 Petri Dish made up of Hydrophobic Polystyrene (PS), Confirm with US FDA Title 21CFR section 177.1640

1.4.2 Complies with the requirement of European Pharmacopoeia, 7th edition (2011) & its supplements 7.5 (07/2012) monographs 3.2.2 Plastic Containers and closures for Pharmaceutical use

1.4.3 The product has passed the USP testing including class VI tests & has been assigned the FDA Drug master file DMF 12123

1.4.4 Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period

1.4.5 Free from heavy metals according to ELV Directive 2000/53/EC, EU CONEG & it's following amendments. It is safe use in contact with food stuff, Pharmaceuticals & drinking water

1.5 Colour: Transparent (Natural colour)

1.6 Quality control

DNase, RNase, and Pyrogen Free

OMARK LIFESCIENCES PVT LTD
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TECHNICAL DATA SHEET

Material Safety Data Sheet

Plastic Petridish for Cat. No.: OMK-PD9015

Product name: 90mm Petri dish, sterile, to be filled with liquid media for microbial culture

1. Identification of the substance/mixture and of the company/undertaking

Company's Name: Omark Lifesciences Pvt Ltd

Location: Noida , Uttar Pradesh ,India

Material: PS (Polystyrene), free of heavy metal

Material use: Raw material for plastics industry

Color :Clear

E-mail address: info@omarklabware.com

2. Hazards identification

Not classified as hazardous. This product contains no hazardous constituents or the concentration of all chemicals constituents are below the regulatory threshold limits

Environment: The product is not considered dangerous for the environment.

3. Composition/information on ingredients

Contains no substance classified as hazardous in concentrations, which should be taken into account according to EC directives.

4. First aid measures

No specific instructions needed.

Skin contact: Cool melted product on skin with plenty of water. Do not remove solidified product.

5. Fire-fighting measures

Suitable extinguishing media: Water in spread jet, dry chemicals, foam or carbon dioxide

Special exposure hazards: Principal toxicant in the smoke is carbon monoxide.

OMARK LIFESCIENCES PVT.LTD
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FACTORY: Plot Number 123, Tech City, Eastern (B) Greater Noida, GB Nagar, Uttar Pradesh-201306 ,India

MSDS

Gamma Sterilization : ISO 11137

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

TEST CERTIFICATE

STERILITY CERTIFICATE

DOSE VALIDATION Gamma Radiation dose is validated according to IS. EN. ISO 11137-2 Method 1 to confirm the SAL 10-6. For that routine testing of bioburden & Sterility test carried out at our manufacturing facility.

VALIDITY OF STERILITY

We assure all sterile products have been sterile through Co-60 gamma radiation with valid certified dose and has been PASSED for all sterility tests. We confirm that the Sterile product would be Sterile until unless the packing pouch is not tampered/punctured/open or 5 yrs from date of Radiation


DNase RNase & Pyrogen Free

- OMARK Confirm that all essential range is "DNase/RNase-free". It can be used for the sensitive applications such as PCR & qPCR.
- DNase and RNase are ubiquitous in the environment, and in some biological materials. They are present in relatively high concentrations.

RNase frequently contaminates common molecular biological reagents such as reaction buffers, enzymes such as reverse transcriptase, RNA polymerase, and buffers for RNA purification and storage.

DNase degrades DNA and its presence is a threat to many molecular biology experiments.

• A deoxy ribonuclease, or DNase, is an enzyme degrades DNA by catalysing the hydrolytic cleavage of phosphodiester linkages in the DNA backbone.

• DNase contamination can come from contact with human skin, and is often present in the lab environment.

• DNase contamination is of great concern in the medical device and pharmaceutical industries as well as the biotech and research fields, because DNase can cause degradation of valuable DNA samples, which may make it impossible to analyse the DNA via PCR, QPCR or next generation sequencing A


Industry Omark Lifesciences
Caters

1. Academic Universities
2. Research Institutes
3. Testing Labs for Environmental sampling
4. Research Labs for Clinical purposes
5. Clinical Labs for Diagnostic issues
6. Science Labs for Forensic Investigation
7. In Labs concerned with public health
8. In repositories of Biological data where they are used as specimen containers.
9. In Labs for Micro Biology
10. In Labs for Biotechnology
11. In Labs concerned with Life Science
12. In the field of Stem Cell Research
13. In Diagnostic Centers and Hospitals
14. In the Environmental and Process Control Industries
15. In the Laboratories of Schools and Colleges
16. In Industrial Laboratories that can be grouped under the following segments

This is to certify that

OMARK LIFESCIENCES PVT LTD
A-38 SECTOR-12 GAUTAM BUDDHA NAGAR
Noida,201301
INDIA

Is now part of Dun & Bradstreet Global Database and has been assigned
D-U-N-S® Number 854242255

If you have any questions about your DUNS Number, please contact us at: SAMHELP@dnb.com for outside the U.S., including Guam, American Samoa and Norther Marianas Islands

GOVT@dnb.com for the U.S., including Puerto Rico and US Virgin Islands
If you have technical difficulties, please contact www.dnb.com/govtduns

Omark

Certificate of Registration

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Quality Management System

of

OMARK LIFESCIENCES PVT. LTD.

at

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has been independently assessed and is compliant with the requirements of:

ISO 9001:2015

For the following scope of activities:

Manufacturing, Marketing and Global Supply of Plastic laboratory Consumables for Research use in Pharmaceutical, Diagnostics, Clinical Research and Other Life Sciences laboratories

Certificate Number: UQ - 2021020515

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

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2nd Surveillance Audit Due	4th February 2023
Certificate Expiry	4th February 2024

Authorised Signatory

Certificate of Registration

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Quality Management System for Medical Devices

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Certificate Expiry	4th February 2024

Authorised Signatory

Certificate of Compliance

CE

Certificate No./ CE/ 12080

Manufacturer

Name : OMARK LIFESCIENCES PVT. LTD.

Address : REGISTERED OFFICE:- A/38, Sector 12, Noida -201301, Uttar Pradesh -201301, India
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3. The certificate validity is conditioned by annual audits or surveillance audits.
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Authorised Signatory

Omark

PHYSICAL PROPERTY OF OMARK LABWARE

Resin	Max Use Temp °C	Brittleness Temp °C	Transparency	Sterilization					Specific Gravity	Flexibility	Water Absorption %
				Autoclaving	Gas	Dry Heat	Radiation	Disinfectant			
HDPE	120	-100	Translucent	No	Yes	No	Yes	Yes	0.95	Rigid	< 0.01
LDPE	80	-100	Translucent	No	Yes	No	Yes	Yes	0.92	Excel	< 0.01
PC	135	-135	Clear	Yes+	Yes	No	No	Yes	1.20	Rigid	0.35
PMMA	50	20	Clear	No	Yes	No	Yes	Some	1.20	Rigid	0.30
PP	135	0	Translucent	Yes	Yes	No	No	Yes	0.90	Rigid	< 0.02
PS	90	20	Clear	No	Yes	No	Yes	Some	1.05	Rigid	0.05
PSF	165	-10	Clear	Yes	Yes	Yes+	Yes	Yes	1.24	Rigid	0.30
PTFE	270	-200	Opaque	Yes	Yes	Yes	No	Yes	2.17	Excel	< 0.01
PVDF	110	-62	Translucent	Yes	Yes	No	No	Yes	1.75	Rigid	0.05
TPX*	175	20	Clear	Yes	Yes	Yes+	No	Yes	0.83	Rigid	< 0.01

Centrifugation: PS – 1400 RCF (With Distilled water at 250C)

Leak Test at 350 mm Hg: No leakage

CHEMICAL PROPERTY OF OMARK LABWARE

Class of Substance at Room Temperature	HDPE	LDPE	PC	PMMA	PP	PS	PSF	PTFE	PVDF	TPX*
Acids, Dilute or Weak	E	E	E	G	E	E	E	E	E	E
Acids, Strong and Concentrated	E	E	N	N	E	F	G	E	E	E
Alcohols, Aliphatic	E	E	G	N	E	E	G	E	E	E
Aldehydes	G	G	F	G	G	N	F	E	E	G
Bases	E	E	N	F	E	E	E	E	E	E
Esters	G	G	N	N	G	N	N	E	G	G
Hydrocarbons, Aliphatic	G	F	F	G	G	N	G	E	E	F
Hydrocarbons, Aromatic	G	F	N	N	F	N	N	E	E	F
Hydrocarbons, Halogenated	F	N	N	N	F	N	N	E	N	N
Ketones	G	G	N	N	G	N	N	E	N	F
Oxidizing Agents, Strong	F	F	N	N	F	N	G	E	G	F

Resin Code	
HDPE	High-density polyethylene
LDPE	Low-density polyethylene
PC	Polycarbonate
PMMA	Polymethyl methacrylate
PP	Polypropylene
PS	Polystyrene
PSF	Polysulfone
PTFE	Polytetrafluoroethylene
PVDF	Polyvinylidene fluoride
TPX*	Polymethylpentene

Chemical Resistance Classification

E = Excellent - 30 days of constant exposure cause no damage. Plastics may even tolerate for years.

G = Good - Little or no damage after 30 days of constant exposure to the reagent.

F = Fair - Some effect after 7 days of constant exposure to the regent like crazing, cacking, loss of strength or discoloration.

N = Not Recommended - Not for continuous use. Immediate damage may occur.

*TPX is the registered Trade Mark of Mitsui & Company Limited

Accreditation Bodies World Wide

S. NO.	ACCREDITAION BODY	COUNTRY
1	Organismo Argentina de Accreditation (OAA)	Argentina
2	National Association of Testing Authorities, Auatralia (NATA)	Australia
3	Bundersministerium fur Wirtchaft, Familie Und Jugend (BMWA)	Austria
4	Belgian Accreditaion Structure (BELAC)	Belgium
5	Coordenacao Geral de Acreditacao General	Brazil
6	Standards Council of Canada (SCC)	Canada
7	Canadian Association for Laboratory Accreditation Inc.(CALA)	Canada
8	China National Accreditation Service for Conformity Assessment (CNAS)	People's Republic of China
9	Ente Costarricense de Accreditaion (ECA)	Costa Richa
10	National Accreditation Body of Republica de Cuba (ONARc)	Cuba
11	Czech Accreditation Institute (CAI)	Czech Republic
12	Danish Accreditation (DANAK)	Denmark
13	Egyptian Accreditation Council (EGAC)	Egypt
14	Finnish Accreditation Service (FINAS)	Finland
15	Comite Francais d'Accreditation (COFRAC)	France
16	Deutsche Akkreditierungsstelle GmbH (DAKKS)	Germany
17	Hellenic Accreditation System S.A. (ESYD)	Greece
18	Oficina Guatemalteca de Accreditacion (OGA)	Guatemala
19	Hong Kong Accreditation Service (HKAS)	Hong Kong China
20	National Accreditation Board for Testing and calibration Laboratories (NABAL)	India
21	National Accreditation Body of Indonesia (KAN)	Indonesia
22	Irish National Accreditation Board (INAB)	Ireland
23	Israel Laboratory Accreditation Authority (ISRAC)	Israel
24	Silstema Italiano di Accreditamento (ACCREDIA)	Italy
25	Consorzio Pubblico per l' Accreditation (COPA)	Italy
26	Japan Accreditation Board for Conformity Assessment (JAB)	Japan
27	International Accreditation Japan (IAJapan)	Japan
28	Voluntary EMC Laboratory Accreditation Center INC (VLAC)	Japan
29	Korea Laboratory Accreditation Scheme (KOLAS)	Republic of Korea
30	Department of standards Malaysia (Standards Malaysia)	Malaysia)
31	entidad mexicana de acreditacion a.c. (ema)	Mexico
32	Dutch New Zealand Council (RvA)	The Netherlands
33	International Accreditation New Zealand (IANZ)	New Zealand
34	Norsk Akkreditering (NA)	Norway
35	Pakistan National Accreditation Council (PNAC)	Pakistan
36	Philippine Accreditation Office (PAO)	Philippines
37	Polish Center for Accreditation (PCA)	Poland
38	Instituto Portugues de Acreditacao (IPAC)	Portungal
39	Romanian Accreditation Association (RENAR)	Romania
40	Association of Analytical Centers "Analitica" (AAC "Analitica")	Russian Federation
41	Singapore Accreditation Council (SAC)	Singapore
42	Slovak National Accreditation Service (SNAS)	Slovakia
43	Slovenian Accreditation (SA)	Slovenia
44	South African National Accreditation System (SANAS)	South Africa

S. NO.	ACCREDITAION BODY	COUNTRY
45	Entidad Nacional de Acrditacion (ENAC)	Spain
46	Sri Lanka Accreditation Board for Conformity Assessment (SLAB)	Sri Lanka
47	Swedish Board for Accreditation and Conformity Assessment (SWEDAC)	Swedan
48	Swiss Accreditation Services (SAS)	Switzerland
49	Taiwan Accreditation Foundation (TAF)	Chinese taipei
50	The Bureau of Laboratory Quality Standards, Department of Medical Science, Ministry of Public Health, Thailand (BLQSDMSc)	Thailand
51	National Standardization Council of Thailand-Office Of the National Accreditation Council (NSC-ONAC)	Thailand
52	Bureau Of Laboratory Accreditation, Department of Science Services, Ministry of Science and Technology (BLA-DSS)	Thailand
53	Tunisian Thailand Council (TUNAC)	Tunisia
54	Turkish Accreditation Agency (TURKAK)	Turkey
55	Dubai Municipality - Accreditation Department (DAC)	United Arab Emirates
56	United Kingdom Accreditation Service (UKAS)	United Kingdom
57	American Association for Laboratory Accreditation (A2LA)	USA
58	National Voluntary Laboratory Accreditation Program (NVLAP)	USA
59	International Accreditation service, Inc (IAS)	USA
60	ANSI-ASQ National Accreditation Board doing Business as A CLASS	USA
61	Laboratory Accreditation Bureau (L-A-B)	USA
62	Perry Johnson Laboratory Accreditation, Inc. (PJLA)	USA
63	American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB)	USA
64	Bureau of Accreditation (BoA)	Vietnam

OMARK LIFESCIENCES PVT LTD
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