

HIMEDIA LABORATORIES PVT. LTD.



Registered office: Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) – 400 604, Maharashtra, India.

This is a multi-site certificate, additional site(s) are listed on the next page(s)

Bureau Veritas Industrial Services (India) Pvt. Ltd. has evaluated the Management System Standard For – Minimizing the Risk of Human DNA Contamination in products to be used to collect, store and analyze biological material for forensic purposes – Requirements.

And is found to be in accordance with the requirements.

Standard

ISO 18385:2016

Minimizing the risk of human DNA contamination in products used to collect, store and analyse biological material for forensic purposes

Scope of certification

Production of Extraction and PCR kits, reagents and consumables for the collection, storage and analysis of biological materials for forensic DNA purposes utilized by the global forensic community.

(As per products listed in Annexure – I)

Original Certification cycle start date: 25 November 2024

Certification cycle start date: 25 November 2024

Subject to the continued satisfactory operation of the organization's Management System, this certificate is valid until: **24 November 2025**

Attestation No. IND.24.804/BA-FS Version: 1 Issue date: 25 November 2024

Authorized Signatory
Jagdheesh N. MANIAN

Director – CERTIFICATION, South Asia Commodities, Industry & Facilities Division

Local office:

Bureau Veritas Industrial Services (India) Pvt. Ltd. 72 Business Park, Marol Industrial Area, MIDC Cross Road "C", Andheri (East), Mumbai – 400 093, India. Pg 1 of 3





HIMEDIA LABORATORIES PVT. LTD.



Standard

ISO 18385:2016

Minimizing the risk of human DNA contamination in products used to collect, store and analyse biological material for forensic purposes

Scope of Assessment

SITE	ADDRESS	SCOPE
Head Office	HIMEDIA LABORATORIES PVT. LTD. Plot No. C-40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) – 400 604, Maharashtra, India.	Production of Extraction and PCR kits, reagents and consumables for the collection, storage and analysis of biological materials for forensic DNA purposes utilized by the global forensic community.
Manufacturing Unit	HIMEDIA LABORATORIES PVT. LTD. B/4-6, MIDC, Palkhed, Dindori, Nashik – 422 202, Maharashtra, India.	Production of Extraction and PCR kits, reagents and consumables for the collection, storage and analysis of biological materials for forensic DNA purposes utilized by the global forensic community.

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Annexure - I

HIMEDIA LABORATORIES PVT. LTD.



Standard

ISO 18385:2016

Minimizing the risk of human DNA contamination in products used to collect, store and analyse biological material for forensic purposes

Scope of Assessment

Sr. No.	Product Name	Product Code under Scope	Type of Product Category
1	HiPurA® Multi sample Pre-filled Plates for Insta NX® Mag32	MB554MPF32200	Extraction Kit
2	HiPurA® Multi sample Pre-filled Plates for DNA Extraction	MB554MPF16200	Extraction Kit
3	HiPurA® Multi sample Pre-filled Cartridges for DNA Extraction	MB554PC16200	Extraction Kit
4	Hi-PCR® Human DNA Quantification Kit	MBPCR266	PCR Kit
5	HiPurA® Molecular Biology Grade Water (for forensic applications)	ML253	Ingredient / Diluent / Component
6	HiPurA® Human DNA Free Swab	MBLA042	Single Use Consumable Kit Componer

