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Certificate

This is to certify that

SHOM HEALTHCARE LLP

PLOT NO B-72, KAMDHENU ESTATE, VILLAGE BAKROL, SUB DISTRICT, ANKLESHWAR, DISTRICT, BHARUCH, GUJARAT PINCODE - 394115

has been independently assessed by SMRC and found to comply with the requirements of:

ISO 13485:2016

(Medical Devices - Quality Management Systems)

For the following scope of activities:

DESIGN AND DEVELOPMENT, MANUFACTURING AND SALES OF IN-VITRO DIAGNOSTIC TEST AND REAGENTS.

Certification Calendar

Certificate No	:	**INQ/AN-17980/3325/1024**
Registered on:	:	**08-10-2024**
Issued on:	:	**08-10-2024**
Expires on:	:	**07-10-2027**

Authorised Signatory

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Certificate

This is to certify that

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PLOT NO B-72, KAMDHENU ESTATE, VILLAGE BAKROL, SUB DISTRICT, ANKLESHWAR, DISTRICT, BHARUCH, GUJARAT PINCODE - 394115

has been independently assessed by SMRC and found to comply with the requirements of:

ISO 9001:2015

(Quality Management System)

For the following scope of activities:

DESIGN AND DEVELOPMENT, MANUFACTURING AND SALES OF IN-VITRO DIAGNOSTIC TEST AND REAGENTS.

Certification Calendar

Certificate No	:	**INQ/AN-17980/3326/1024**
Registered on:	:	**08-10-2024**
Issued on:	:	**08-10-2024**
Expires on:	:	**07-10-2027**

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Certificate Of Compliance

We hereby declare that the technical file of the product complies with the requirements of Medical Device Directive (MDD) 93/42/EEC.

Name: **SHOM HEALTHCARE LLP**

Address: **PLOT NO B-72, KAMDHENU ESTATE, VILLAGE BAKROL, SUB DISTRICT, ANKLESHWAR, DISTRICT BHARUCH, GUJARAT PINCODE - 394115**

Products: **DENGUE ANTIBODY AND ANTIGEN COMBO TEST, DENGUE ANTIBODY TEST, DENGUE NS1 ANTIGEN TEST, HIV-HCV-HBSAG COMBO RAPID TEST, MALARIA PF (HRP2)/PAN (PLDH) ANTIGEN TEST, MALARIA PF (HRP2)/PV (PLDH) ANTIGEN TEST, INFLUENZA A+B RAPID TEST.**

Complies with the applicable requirements

The certification body has conducted an audit of the quality system for the aforementioned product, encompassing its design, manufacturing process, and final inspection. The quality system has been evaluated, approved, and is under continuous surveillance in accordance with Medical Device Directive (MDD) 93/42/EEC.

This certificate is issued under the following conditions:

This applies solely to the quality system maintained in the manufacturing of the referenced models mentioned above, and it does not replace the design or type-examination procedures, if requested

1. The certificate remains valid until changes occur in the manufacturing conditions or the quality systems
2. The certificate validity is conditioned by positive results or surveillance audits.
3. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
4. 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 sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at https://ukga.org.uk

Certification Calendar

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