DEALER'S LICENCE - Manufacturer

Licence No. : ES0501372 **Approved Date : 12/03/2021**

Job Reference No. : MD21780825T **Expiry Date : 11/03/2023**

1. COMPANY INFO

CALMEDIX MANUFACTURING PTE LTD (Unique Entity No.(UEN) : 202025625N)

23 TAGORE LANE, #04-09, TAGORE 23 WAREHOUSE, SINGAPORE (787601)

Main Tel. No. : 64520300, Fax No. : 64520500

Contact Person : Vikram Ayyadurai, Contact Tel. No. : 64597834

Contact Email : vikram@cal-medix.com

2. LICENCE INFO

Manufacturer (CLASS A)

Approved Site Address(es) -

Certification	Quality Systems	Certification Body	Expiry Date
	ISO13485	Guardian Independent Certification Pte Ltd	25/02/2024

Approved Scope of Operations Manufacture, Storage and Distribution of Non-Sterile Medical Face Masks

3. CONDITION(S) OF APPROVAL

1 DLC018 - The holder of this licence shall comply with all requirements under the Health Products Act and the Health Products (Medical Devices) Regulations 2010.

2 DLC019 - Upon request by the Authority, the holder of this licence shall submit medical devices for batch testing in accordance to a product standard prescribed by the Authority, to a testing body recognised by the Authority as stipulated in the Health Products (Medical Devices) Regulations 2010.

3 DLC020 - The holder of this licence shall be subject to a renewal fee, as stipulated in the Health Products (Medical Devices) Regulations 2010. Failure to pay the renewal fee within the allocated payment period would result in the expiry of the licence.

4 DLC022 - Any changes to this licence that are reportable under Regulation 48 of the Health Products (Medical Devices) Regulations 2010, including changes to the name of the company, address and GDPMDS/ISO 13485 certification of the licencee, shall have to be notified to the Authority no later than 15 days after the date of implementation of the change. Failure to notify the Authority within 15 days would invalidate this licence with immediate effect.

5 DLC023 - The holder of this licence shall not use this licence in any form of advertisement.

6 DLC037 - The holder of this licence shall ensure that the ISO13485 audit report is submitted to the Authority, where required by the Authority. The audit report shall be submitted to the Authority within the timeframe set by the Authority, which would be a minimum of 5 working days.

7 DLC038 - The activities performed by the licence holder shall be confined to the scope of its valid ISO 13485 certificate or scope of their ISO 13485 quality system. Any activity performed under this licence shall be confined to facilities certified to ISO 13485 or covered under the ISO 13485 quality system.

8 DLC044 - The holder of this licence shall submit the list of Class A medical devices manufactured and/or imported, as applicable, by the licence holder, in accordance with the format specified by the Authority prior to import and/or supply in Singapore of the Class A devices.

REMARKS 1: -

REMARKS 2: -

The above information is current as of the date of print : 23/02/2022

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