



Letter of Designation

ISSUING AGENCY DESIGNATION

Date: 15th July 2022

Ref No: HSA-002-HIBCC

Dear HIBCC,

Health Sciences Authority (HSA) acknowledges the receipt of your Issuing Agency Declaration dated 1st July 2022 and hereby designates **Health Industry Business Communications Council (HIBCC)** to act as an Issuing Agency for the assignment of Unique Device Identifiers (UDI) for medical devices imported/manufactured and supplied in Singapore.

This designation letter authorizes **HIBCC** to assign UDI in the context of Medical Device Unique Device Identification system in Singapore.

Your responsibilities as a designated issuing agency includes the following:

- i) Meeting the criteria set forth and acknowledged in the Issuing Agency Declaration dated 1st July 2022
- ii) Notifying HSA before implementing any changes to the format or structure of the UDI
- iii) Should there be a change in HIBCC point of contact with HSA pertaining to UDI or Issuing Agency Designation matters, HIBCC is obligated to inform HSA within 7 calendar days.

HSA reserves the right to review this designation as and when necessary. HSA may cancel this designation if the issuing agency has failed to fulfil its responsibilities or meet any of the criteria set forth in the Issuing Agency Declaration.

MEDICAL DEVICES CLUSTER
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY