



FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2023/000009

1. M/s HealthCubed India Pvt. Ltd, Site No. 38 & 39, Begur hobli, Hongasandra Dhakle, Garvebhavi Palya, Bengaluru UrbanBengaluru, Bengaluru (Bangalore) Urban, Karnataka (India) - 560068 Telephone No.: 01148300300 FAX: 01148300300 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s HealthCubed India Private Limited, Site No 38 & 39, Begur Hobli, Hongasandra Dhakle, Garvebhavi Palya, Bengaluru, Karnataka, India 560068, Bengaluru (Bangalore) Urban, Karnataka (India) - 560068 Telephone No.: 011-48300300 FAX: 011-48300300
2. Details of medical device(s) [Annexed]
3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer
4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

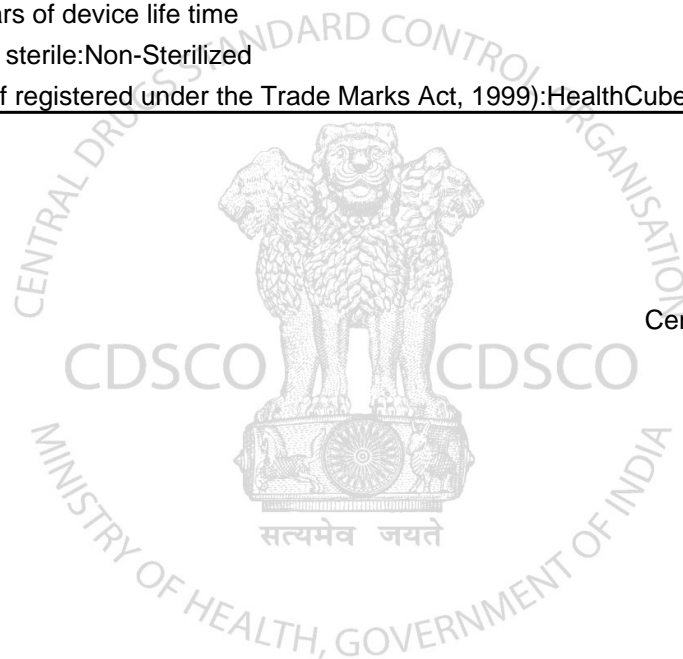
ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name: Multiparametric point of care device Model No.: HC 2006-A - NA , HC 2020 - NA Intended Use: Indications for Use (XL) HealthCube XL is an integrated device which assists in measuring qualitative and quantitative physiological and biological parameters from the human body and finger stick blood. The device has a 12 Channel ECG modules to measure and interpret the electrical signals produced by the heart. Non-invasive measurement of Blood Oxygen saturation (SpO₂) and pulse rate. Non-invasive measurement of Blood Pressure (BP) Measurement of Blood Glucose, Total Cholesterol (Chol), Uric Acid (UA) and Hemoglobin (Hb) Optical system that captures the image of the Rapid Diagnostics Tests (RDT) and allows user to record the result. The HealthCube XL system communicates with mobile device through Bluetooth communication. Note: The output from the device shall not be considered for any final diagnosis and a Medical Professional opinion shall be taken before any clinical intervention. Note: - The outcome of the device is not to be used as a final decision-making. Class of medical device: Class C Material of construction: The entire device is made of Aluminum 5052 which is a medical grade material. Dimension (if any): 310mm*248mm*138mm Shelflife: 3 years of device life time Sterile or Non sterile: Non-Sterilized Brand Name (if registered under the Trade Marks Act, 1999): HealthCube XL</p>

2	<p>Generic Name: Multiparametric point of care device</p> <p>Model No.: HC 2002-A - NA , HC 2010 - NA</p> <p>Intended Use: Indication For Use (HealthCube SE): HealthCube - SE is an integrated device which assists in measuring qualitative and quantitative physiological and biological parameters from the human body and finger stick blood. The device has a Non-invasive measurement of Blood Oxygen Saturation (SPO2) and pulse rate. Non-invasive measurement of Blood Pressure. Measurement of Blood Glucose, Total Cholesterol, Uric Acid and Haemoglobin. Optical system that captures the image of the Rapid Diagnostics Tests and allows user to record the result. The HealthCube - SE system communicates with mobile device through Bluetooth communication. Note: The output from the device shall not be considered for any final diagnosis and a Medical Professional opinion shall be taken before any clinical intervention.</p> <p>Class of medical device: Class C</p> <p>Material of construction: The entire device is made of Aluminum 5052 which is a medical grade material.</p> <p>Dimension (if any): 310mm*248mm*138mm</p> <p>Shelflife: 3 years of device life time</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name (if registered under the Trade Marks Act, 1999): HealthCube SE</p>
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Place:

Date 23-Jan-23



Central Licensing Authority