

FORM MD-15

[See sub-rule (1) of rule 36]

Licence to Import Medical Device

Licence No. : IMP/MD/2023/000785

1. M/s Taevas Life Sciences Private Limited, H.No. 20-M/733A and 734/1 and 734/2/SGE/501, Fifth Floor, Sai Ganesh Enclave, Matrusri Cooperative House Building Society Limited, Miyapur (V), Serilingampally (M) , Ranga Reddy, Telangana (India) - 500049 Telephone No.: 1800-123-954000 FAX: 1800-123-954000 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of overseas manufacturer and manufacturing site under this licence

S.No	Name and Address of Manufacturer	Name and Address of Manufacturing Site
1	Legal Manufacturing Site : M/s Circle Cardiovascular Imaging Inc., 800 5 Ave SW No.1100 Calgary AB T2P 3T6 Calgary Alberta, Country: Canada Telephone No.: 1-403-338-1870 FAX: 1-403- 338-1870 E-Mail : legal@circlecvi.com	Actual Manufacturing Site : M/s Circle Cardiovascular Imaging Inc., 800 5 Ave SW No.1100 Calgary AB T2P 3T6 Calgary Alberta, Country: Canada Telephone No.: 1-403-338-1870 FAX: 1-403-338- 1870 E-Mail : legal@circlecvi.com

3. Details of medical device(s):

S.No	Medical Device Details
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1

1. Generic Name :MRI system application software, CT system application software
2. Brand Name(if registered under the Trade Marks Act, 1999) :cvi42
3. Class of Medical Device :Class C
4. Shelf Life :NIL
5. Sterile/Non-sterile:Non-Sterilized
6. Intended Use :cvi42 is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) images and cardiovascular computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables:
 - Importing cardiac MR & CT Images in DICOM format.
 - Supporting clinical diagnostics by qualitative analysis of cardiac MR & CT images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases, 3D reconstruction of images including multiplanar reconstructions of the images.
 - Supporting clinical diagnostics by quantitative measurement of the heart and adjacent vessels in cardiac MR & CT images*, specifically signal intensity, distance, area, volume and mass.
 - Supporting clinical diagnostics by using area and volume measurements for measuring LV function and derived parameters cardiac output and cardiac index in long axis and short axis cardiac MR & CT images.
 - Flow quantifications based on velocity encoded cardiac MR images including 4D flow analysis
 - Tissue characterization of cardiac MR Images**
 - Perfusion analysis of cardiac MR Images**
 - Strain analysis of cardiac MR images **
 - Supporting clinical diagnostics of cardiac CT images including quantitative measurements of calcified plaques in the coronary arteries (calcium scoring), specifically Agatston and volume and mass calcium scores, evaluation of heart structures including coronaries, femoral, aortic and mitral values.
 - Evaluating CT and MR images of blood vessels. Combining digital image processing and visualization tools such as multiplanar reconstruction (MPR), thin/thick maximum intensity projection (MIP), inverted MIP thin/thick, volume rendering technique (VRT), curved planner reformation (CPR), processing tools such as bone removal (based on both single energy and dual energy) table removal and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics) and key images).

The software package is designed to support the physician in conforming the presence or absence of physician identified lesion in blood vessels and evaluation, documentation and follow up of any such lesions. cvi42 shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR or CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. cvi42 is a software application that can be used as a stand-alone product or in a networked environment. The target population for cvi42 is not restricted, however the image acquisition by a cardiac magnetic resonance scanner may limit the use of the software for certain sectors of the general public. cvi42 shall not be used to view or analyze images of any part of the body except the cardiac images acquired from a cardiovascular magnetic resonance or computed tomography scanner. *Quantitative analysis is dependent on the quality and correctness of the image source data. **The Tissue Characterization, Strain and Perfusion modules are not available for clinical use in the USA.
7. Material of Construction: Not Applicable
8. Dimension: Not Applicable
9. Model No. :Version 5.14 - cvi42- Software as a Medical Device (SaMD)
10. Accessory/Components :NIL

2	<p>1. Generic Name :Software for Visualization of Vascular Anatomy and Intravascular Devices Visualization</p> <p>2. Brand Name(if registered under the Trade Marks Act, 1999) :TruPlan</p> <p>3. Class of Medical Device :Class C</p> <p>4. Shelf Life :NIL</p> <p>5. Sterile/Non-sterile:Non-Sterilized</p> <p>6. Intended Use :TruPlan enables visualization and measurement of structures of the heart and vessels for pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure. To facilitate the above, TruPlan provides general functionality such as: • Segmentation of cardiovascular structures • Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR • Simulation of TEE views, ICE views, and fluoroscopic rendering • Measurement and annotation tools • Reporting tools TruPlan's intended patient population is comprised of adult patients.</p> <p>7. Material of Construction: Not Applicable</p> <p>8. Dimension: Not Applicable</p> <p>9. Model No. :Version 2.0 - TruPlan- Software as a Medical Device (SaMD)</p> <p>10. Accessory/Components :NIL</p>
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4. The authorised agent M/s Taervas Life Sciences Private Limited, H.No. 20-M/733A and 734/1 and 734/2/SGE/501, Fifth Floor, Sai Ganesh Enclave, Matrusri Cooperative House Building Society Limited, Miyapur (V), Serilingampally (M) , Ranga Reddy, Telangana (India) - 500049 Telephone No.: 1800-123-954000 FAX: 1800-123-954000 will be responsible for the bussines activities of the overseas manufacturer, in India in all respects.

5. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: New Delhi

Central Licensing Authority

