

FORM MD-15

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

Licence to Import Medical Device

Licence No. : IMP/MD/2024/000519

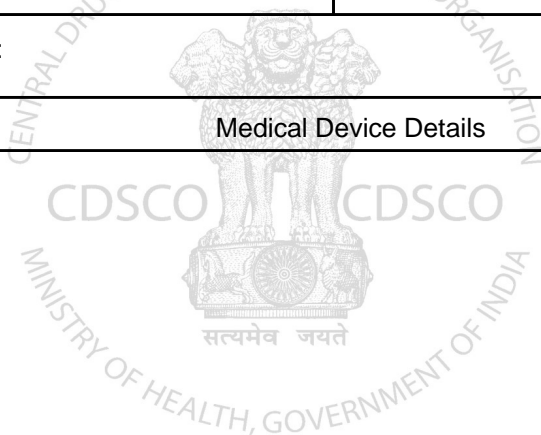
1. M/s MODI MEDICARE, 341, Kailas Plaza, 1/20, Kailas Plaza Premises Coop Ltd, Vallabhbaug Lane, Ghatkopar East , Mumbai Suburban, Maharashtra (India) - 400075 Telephone No.: 9324809990 FAX: 9324809990 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing 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 Intrasense, 1231 avenue du Mondial 98, 34000 Montpellier , Country: France Telephone No.: 336 29 21 69 41 FAX: 334 67 13 01 32 E-Mail : Nicolas.difrancesco@intrasense. fr	Actual Manufacturing Site : M/s Intrasense, 1231 avenue du Mondial 98, 34000 Montpellier, Country: France Telephone No.: 336 29 21 69 41 FAX: 334 67 13 01 32 E-Mail : Nicolas.difrancesco@intrasense.fr

3. Details of medical device(s):

S.No	Medical Device Details
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1. Generic Name :Myrian
2. Brand Name(if registered under the Trade Marks Act, 1999) :Myrian
3. Class of Medical Device :Class B
4. Shelf Life :NIL
5. Sterile/Non-sterile:Non-Sterilized
6. Intended Use :Myrian® is a medical device software for processing, management, advanced visualization and analysis of multimodality medical images. Myrian® is intended to provide information which is used to take decisions with diagnosis or therapeutic purposes.
7. Material of Construction: Not Applicable
8. Dimension: NA
9. Model No. :Myrian 2.9.13 - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian Expert - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian Expert VL - software for processing, management, advanced visualization and analysis of multimodality medical images, Myrian XM-MR - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XM-CT - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XM-XR - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XM-NM - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-Liver - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-Lung - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-Ortho - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-LungNodule - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-Colon - software for processing, management, advanced visualization and analysis of multimodality medical images, Myrian XP-Breast - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-Prostate - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-FemalePelvis - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-LiverMRI - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-AbdoFat - software for processing, management, advanced visualization and analysis of multimodality medical images, Myrian XP-Vessel - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-Cardiac - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XP-Ablation - software for processing, management, advanced visualization and analysis of multimodality medical images, Myrian XP-Mammo - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XL-Onco - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XL-Matching - software for processing, management, advanced visualization and analysis of multimodality medical images, Myrian XL-TumorBoard - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian XL-Permeability - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian eCRF - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian RConnector - software for processing, management, advanced visualization and analysis of multimodality medical images,Myrian ROICreator - software for processing,

management, advanced visualization and analysis of multimodality medical images, Myrian QuizCreator - software for processing, management, advanced visualization and analysis of multimodality medical images, Myrian 21CFRPart 11 - software for processing, management, advanced visualization and analysis of multimodality medical images
10. Accessory/Components :NIL



4. The authorised agent M/s MODI MEDICARE, 341, Kailas Plaza, 1/20, Kailas Plaza Premises Coop Ltd, Vallabhbaug Lane, Ghatkopar East , Mumbai Suburban, Maharashtra (India) - 400075 Telephone No.: 9324809990 FAX: 9324809990 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

