EC Certificate Full Quality Assurance System: Certificate PL19/1102977400

The management system of

Unitary Enterprise ADANI

7 Selitsky Str., 220075 Minsk, Belarus

has been assessed and certified as meeting the requirements of

Digitally signed by Savca Octavian
Date: 2021.08.20 09:13:16 EEST
Reason: MoldSign Signature
Location: Moldova

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 03 July 2020 until 17 January 2022
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 11 September 2002
and first certified by SGS Belgium NV since 16 December 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered PL/WAW PL00144a

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Unitary Enterprise ADANI

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Digital X-Ray Diagnostic Systems with Acquisition & Diagnostic Computer Workstations:
1) PULMOSCAN Chest Digital Radiography System (family) for generating x-ray images of the chest organs for screening and diagnosis purposes.
2) MAMMOSCAN Full Field Digital Mammography (FFDM) System for producing mammographic images for screening and diagnosis of breast cancer.
3) UNIEXPERT 2 PLUS Radiography Room System for acquiring standard size X-ray images of osseous structures and soft tissues.

X-ray Therapy Systems with Operator's Automated Workstation:
1) THERAD 200 X-ray Therapy System for superficial and depth radiotherapy.
2) THERAD 100 X-ray Therapy System for superficial radiotherapy.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

Novodvorsky county, 116, 223063, Minsk region, SEZ "Shabany", Belarus

CERTIFICATE

No. 3750155

LL-C Certification

This is to certify the Quality Management System of

ADANI
from ideas to solutions

Unitary Enterprise «ADANI»

st. Selitskogo, 7
220075 Minsk
Republic of Belarus

Production sites:
JSC «ADANI TECHNOLOGIES», Novodvorsky s/s, 116 Minsk, 223063
Unitary Enterprise «ADANI», Novodvorsky s/s, 116 Minsk, 223063

has been assessed and found to be in compliance with the Standard

ISO 9001:2015

applicable to

Design, development, manufacturing, assembling and service of devices and equipment based on using of X-ray, ionizing and electromagnetic radiation

The certificate has been issued under No. **3750155** for the registration period from 14 December 2020 to 13 December 2023.

Approved by

Printed by

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

S 3137

SECURITY · ENVIRONMENT · QUALITY
LL-C Certification

validity code **83AD0B05-DCA**
Check the validity of this certificate using this code at **www.ll-c.info**

CERTIFICATE

No. 3750155

LL-C Certification

This is to certify the Quality Management System for Medical Devices of the company

ADANI
from ideas to solutions

Unitary Enterprise «ADANI»

st. Selitskogo, 7
220075 Minsk
Republic of Belarus

Production sites:
JSC «ADANI TECHNOLOGIES», Novodvorsky s/s, 116 Minsk, 223063
Unitary Enterprise «ADANI», Novodvorsky s/s, 116 Minsk, 223063

has been assessed and found to be in compliance with the Standard

EN ISO 13485:2016

applicable to

Design, development, manufacturing, assembling and service of medical devices utilizing ionizing radiation

The certificate has been issued under No. **3750155** for the registration period from 14 December 2020 to 13 December 2023.

Approved by

Printed by

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

S 3137

SECURITY · ENVIRONMENT · QUALITY · SAFETY
LL-C Certification

validity code **69A55F22-A5B**
Check the validity of this certificate using this code at **www.ll-c.info**

ЕВРАЗИЙСКИЙ ЭКОНОМИЧЕСКИЙ СОЮЗ

ДЕКЛАРАЦИЯ О СООТВЕТСТВИИ

Заявитель Научно-производственное частное унитарное предприятие "АДАНИ",
зарегистрирован в Едином государственном регистре юридических лиц и индивидуальных предпринимателей за №100054851,
место нахождения (адрес юридического лица): Республика Беларусь, Минская обл., 220075, г. Минск, ул. Селицкого, 7,
номер телефона: +375173490000, адрес электронной почты: info@adani.by
в лице заместителя генерального директора по техническому развитию Сосенко Константина Викторовича (Доверенность № 43/17 от 08.09.2017)
заявляет, что Аппарат рентгеновский маммографический «МАММОСКАН», изготавливаемый по ТУ BY 100054851.045-2008 «Аппарат рентгеновский маммографический «МАММОСКАН»»,
изготовитель: Научно-производственное частное унитарное предприятие «АДАНИ»,
место нахождения (адрес юридического лица): Республика Беларусь, 220075, г. Минск, ул. Селицкого, 7,
Код ТН ВЭД ТС: 9022 14 000 0, серийный выпуск,

соответствует требованиям технического регламента Таможенного союза ТР ТС 020/2011 «Электромагнитная совместимость технических средств»

Декларация о соответствии принята на основании: протокол испытаний № 43-18/0032-1-2018 от 12.01.2018, выданный Научно-исследовательским центром испытаний средств измерений и техники республиканского унитарного предприятия «Белорусский государственный институт метрологии», аттестат аккредитации № BY/112 02.1.0.0025, протокол испытаний № 45-18/0032-3-2018 от 30.01.2018, выданный Научно-исследовательским центром испытаний средств измерений и техники республиканского унитарного предприятия «Белорусский государственный институт метрологии», аттестат аккредитации № BY/112 02.1.0.0025; сертификат системы менеджмента качества № PL18/0655 от 17.01.2018, выданный SGS United Kingdom Ltd., Соединенное королевство Великобритании и Северной Ирландии, аттестат аккредитации № 140, сертификат системы менеджмента качества № PL02/56837.00 от 02.02.2018, выданный SGS United Kingdom Ltd., Соединенное королевство Великобритании и Северной Ирландии, аттестат аккредитации № 140.
Схема декларирования соответствия – 6Д.

Дополнительная информация:
СТБ МЭК 60601-1-2-2006 «Изделия медицинские электрические. Часть 1-2. Общие требования безопасности. Электромагнитная совместимость. Требования и методы испытаний», СТБ EN 55011-2012 «Электромагнитная совместимость. Радиопомехи от промышленных, научных и медицинских (ПНМ) высокочастотных устройств. Нормы и методы измерений».

Аппарат должен храниться по условиям хранения 1 ГОСТ 15150-69 при температуре воздуха от плюс 5 °С до плюс 40 °С и максимальной относительной влажности воздуха 80 % при температуре плюс 25 °С. Полный средний срок службы аппарата должен быть не менее 8 лет. Гарантийный срок эксплуатации аппарата – 18 месяцев со дня ввода в эксплуатацию. Исчисление гарантийного срока эксплуатации начинается не позднее 6 месяцев со дня поступления аппарата потребителю.

Декларация о соответствии действительна с даты регистрации по 27.02.2023 включительно.

Сосенко Константин Викторович

(подпись) М.П. (Ф. И. О. заявителя)

Регистрационный номер декларации о соответствии:
ЕАЭС №BY/112 11.01. ТР020 000 02410
Дата регистрации декларации о соответствии:01.03.2018

ADANI
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
NAPLES FL 34114

October 20, 2017

Re: K172027
Trade/Device Name: Adani MammoScan
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: September 18, 2017
Received: September 21, 2017

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure