EC Certificate Full Quality Assurance System: PL02/56836.00

The management system of

ADANI UP

7 Selitsky Str., 220075 Minsk, Belarus

has been assessed and certified as meeting the requirements of

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 16 December 2016 until 17 January 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 17 November 2017
Issue 11. Certified since 11 September 2002

Certification is based on reports numbered PL/WAW-PL00144a

Authorised by

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ADANI UP

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 11

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.**

Цифровые рентгенодиагностические системы с компьютерными рабочими станциями оператора и врача-рентгенолога:

1. **ПУЛЬМОСКАН - цифровые рентгенографические системы для обследования органов грудной клетки (семейство).**
2. **МАММОСКАН - цифровые рентгеновские маммографические системы для скрининга и обследования рака молочной груди (семейство).**

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