EC Certificate Full Quality Assurance System: PL02/56836.00

The management system of

Unitary Enterprise ADANI

7 Selitsky Str., Minsk, 220075, 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

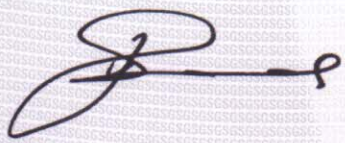
The scope of registration appears on page 2 of this certificate.

This certificate is valid from 12 July 2018 until 17 January 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 17 November 2020
Issue 12. Certified since 11 September 2002

Certification is based on reports numbered PL/WAW-PL00144a

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

Authorised by



SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 02 0315 M2

Unitary Enterprise ADANI

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 12

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.

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