EC Certificate Full Quality Assurance System: Certificate KR19/81826250

The management system of

DRTECH Corporation.

Suite No.1, 1 Floor & Suite No. 2, 3 Floor, 29,
Dunchon-Daero 541beon-gil, Jungwon-gu, Seongnam-si,
Gyeonggi-do, 13216, Republic of Korea

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 2019 until 15 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 22 June 2012
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 KR/SEL Y-PC/11273

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

DRTECH Corporation.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Flat-Panel Digital X-Ray Detectors (EVS 4343, EVS 3643, RSM 1824C, EVS 3643G, EVS 4343G, RSM 2430C, EVS 2430W, EVS 2430GW, EVS 4343A, EVS 4343AG, EVS 4343W, EVS 4343WG, EVS 3643A, EVS 3643AG, EVS 3643W, EVS 3643WG, RSM 1824S, RSM 1824P, EXPD 4343P, EXPD 3643P, EVS 4343WP, EVS 3643WP, RSM 2430P);

Radiological Image Processing System (EConsole1, RConsole1)

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

(Head Office) 2F/ 6F, SPG blg.,166, jeongjail-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13558, Republic of Korea,