

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60134971 0001

Report No.: 28242324 002

Manufacturer: Kinepict Health Kft
Kelta köz 5.
2092 Budakeszi
Hungary

Products: - Standalone software for angiography images
processing and viewing

(See attachment for site included)

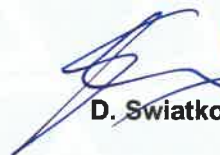
Expiry Date: 2023-06-20

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-02-22

Date: 2019-02-22

Notified Body



D. Swiatko



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60134971 0001
Report No.: 28242324 002

Manufacturer: Kinepict Health Kft
Kelta köz 5.
2092 Budakeszi
Hungary



Site included:

Kinepict Health Kft
Júlia u. 11
1026 Budapest
Hungary

Activity: Design / development and manufacture

Date: 2019-02-22

Notified Body



D. Swiatko

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Kinepict Health Kft
Kelta köz 5.
2092 Budakeszi
Hungary

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, manufacture, distribution
and maintenance services of standalone software
for angiography images processing and viewing**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-02-22
Certificate Registration No.: SX 60134972 0001
An audit was performed. Report No.: 28242324 002
This Certificate is valid until: 2021-06-20

Certification Body



Date 2019-02-22



D. Swiatko

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60134972 0001
Report No.: 28242324 002

Organization: Kinepict Health Kft
Kelta köz 5.
2092 Budakeszi
Hungary

Scope:

Site included:

Kinepict Health Kft
Júlia u. 11
26 Budapest
Hungary

Activity: Design and development, manufacture, distribution
and maintenance services of standalone software
for angiography images processing and viewing

Certification Body



Date: 2019-02-22

D. Swiatko