TÜVRheinland®

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
TÜVRheinland®
Zertifizierungsstelle

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.

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Doc. 1/1, Rev. 0

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

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

D. Swiatko

Date: 2019-02-22

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-02-22

D. Swiatko

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜVRheinland®

Doc. 1/1, Rev. 0

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certification Body

TÜVRheinland LGA Products GmbH ® TÜVRheinland Zertifizierungsstelle

Date: 2019-02-22

D. Swiatko