

EC CERTIFICATE
Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-866-200-1906

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the manufacturer:

Control-X Medical Kft.
Öv utca 29.
1141 Budapest
Hungary

for the products / product category:

Diagnostic X-ray equipment

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **NE/1041/2020**

This certificate is valid until **2024-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 4

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 19 June 2019.

Budapest, 2021-01-28


László Imre
Managing Director



EMKI 2664

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu

ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 5-866-200-1906

The certificate is valid for the following products / models:

Diagnostic X-ray equipment

Class

Perform-X radiographic systems including the following configurations:

I Ib

- Perform-X F100/F200/F300/F400 Floor Mounted Radiographic System
- Perform-X C100/C200/C300/C400 Ceiling Mounted Radiographic System
- Perform-X Chest Radiographic System
- RadioLogiX Radiographic System

consisting of the following components:

- Milestone HF X-ray generators
- STYLIX and PHOENIX radiographic tables
- WS 99 wall stands
- TS 99 tube stands
- CTM-200 tube stands

Z-Motion radiographic system

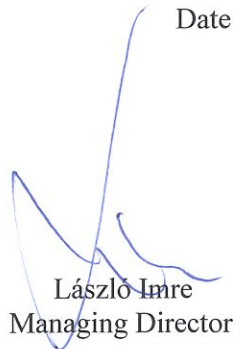
I Ib

- Z-Motion universal digital radiographic stand
- Milestone HF X-ray generators

Issue: 4

Date: 2021-01-28

First issued: 2019-06-19


László Imre
Managing Director



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