



MEDEXCOM-TEH SRL
IDNO 1019600008809
Str. Cuza-Vodă 44, of.111, mun. Chisinau,
Republica Moldova

nr. 02-66 din 14.07.2020

IMSP Spitalul Clinic Republican "Timofei Moșneaga"

achizitiipublicescr@gmail.com

Prin prezenta, compania MEDEXCOM-TEH SRL, urmare a desfășurării licitației deschise nr. ocds-b3wdp1-MD-1593162394889 din 26.06.2020 privind *"pieselor de schimb, accesoriilor și consumabilelor pentru mentenanța dispozitivelor medicale etapa II, pentru anul 2020"*, Vă prezintă atașat certificatele solicitate.

Anexă: - Certificat CE producător CANON MEDICAL SYSTEMS – 2 file;

- Certificat ISO 13485 producător CANON MEDICAL SYSTEMS – 2 file.

Cu respect,

Administrator

Vasile MATEI

EC Certificate

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

Registration No.: HD 60143874 0001

Report No.: 12031293 014

Manufacturer: **Canon Medical Systems Corporation**
1385, Shimoishigami
Otawara-shi, Tochigi
324-8550 Japan

Products: see attachment for products included

Replaces Approval, Registration No.: HD 60125549 0001

Expiry Date: 2024-05-26

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: 2019-11-07

Date: 2019-11-07



Notified Body


M.Sc. M. Aihara

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

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60143874 0001
Report No.: 12031293 014

Manufacturer: **Canon Medical Systems Corporation**
1385, Shimoishigami
Otawara-shi, Tochigi
324-8550 Japan

Products included:

- Mobile and Stationary Diagnostic X-Ray Systems
- Mobile and Stationary Fluoroscopic X-Ray Systems
- X-Ray Computed Tomography Systems
- **Diagnostic Ultrasound Systems**
- Magnetic Resonance Imaging Systems
- Positron CT System combined with X-ray CT Scanner
- Workstation Software for Diagnostic X-Ray Systems
- Workstation Software for Diagnostic X-Ray Computed Tomography Systems
- Workstation Software for Diagnostic Ultrasound Systems
- Workstation Software for Diagnostic Magnetic Resonance Imaging Systems



Notified Body

Date: 2019-11-07


M.Sc. M. Aihara

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Canon Medical Systems Europe B.V.

**Zilverstraat 1
2718 RP Zoetermeer
The Netherlands**

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

**Marketing, sales, distribution, installation, maintenance,
servicing, training and general support of
medical diagnostic imaging related equipment
(see attachment for subsidiaries included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

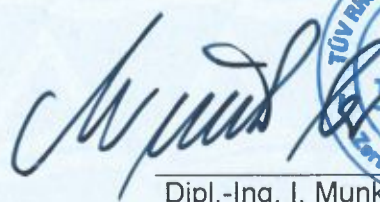
are fulfilled. The quality management system is subject to yearly surveillance.

This Certificate is valid from:	2018-08-20
Certificate Registration No.:	SX 60131519 0001
An audit was performed. Report No.:	21196527 009
This Certificate is valid until:	2021-08-19

Certification Body



Date 2018-08-15


Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg

Tel.: (+49/221) 8 06 - 13 71 Fax: (+49/221) 8 06 - 39 35 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

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

**Attachment to
Registration No.:
Report No.:**

**SX 60131519 0001
21196527 009**

Organization:

**Canon Medical Systems Europe B.V.
Zilverstraat 1
2718 RP Zoetermeer
The Netherlands**

Scope:

**Marketing, sales, distribution, installation, maintenance,
servicing, training and general support of medical diagnostic
imaging related equipment**

Subsidiary:

**Canon Medical Systems GmbH
Industriezentrum NÖ-Süd
Ricoweg 40
2351 Wiener Neudorf
Austria**



Date: 2018-08-15



Dipl.-Ing. I. Munkler

