145132-21-05-18

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Kft. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Contact Co., Ltd.

Registration:	**7 Hetmana Polubotka str., 14000 Chernihiv, Ukraine**
Headquarters:	**21 Stepana Bandery ave., 04655 Kyiv, Ukraine**
Manufacturing plant:	**20 Polarna str., 04655 Kyiv, Ukraine**
Authorised representative:	**EMBITRON s.r.o., č.p. 290, 330 23 Vochov, Czech Republic**

Scope:

Electrosurgical Generator Units

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Electrosurgical Generator unit	ECONT-0201.1	electrosurgical treatment	ECONT-0201	II.b
	ECONT-0201.2			
	ECONT-0201.3			
Electrosurgical Generator unit with Argon Supply Unit ECONT-0201.3A	ECONT-0201.3 & ECONT-0201.3A			

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 156-CE-170220

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Issue: 1
Issued: 18 May 2021
First issued: 18 May 2021
Start date of certified status: 18 May 2021
Expires:
25 May 2024

Valter PAPP, Dr.
General Manager

Digitally signed by Jighili Tatiana
Date: 2021.06.25 17:28:14 EEST
Reason: MoldSign Signature
Location: Moldova

CE Certiso Ltd. NB2409 Notified Body

CE Certiso Kft.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate number: 144994-20-04-15

Name of certified organisation:

Contact Co., Ltd.

Registration:	**7 Hetmana Polubotka str., 14000 Chernihiv, Ukraine**
Headquarters:	**21 Stepana Bandery ave., 04655 Kyiv, Ukraine**
Manufacturing plant:	**20 Polarna str., 04655 Kyiv, Ukraine**

Scope:

Design, manufacture, sale, delivery and service of active surgical devices

CE Certiso Ltd. certifies that the quality management system applied by the organisation above meets the requirements of the following standard on the listed scope:

MSZ EN ISO 13485:2016
(ISO 13485:2016)

Issue: 1
Issued: 15 April 2020
First issued: 15 April 2020
Start date of certified status: 08 August 2017

Expires:
14 April 2023

Valter PAPP, dr.
General Manager

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

ISO 13485

NAH-4-0136/2019
MANAGEMENT SYSTEM CERTIFICATION BODY

CE Certiso Ltd.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu

Contact
medical innovations

ISO 13485:2016

EC DECLARATION OF CONFORMITY No DC/07-07/20
EU Directive 93/42/EEC/A5 as amended

Name and address of the manufacturer:
Contact Co., ltd.
21 S. Bandery ave., 04655 Kyiv, Ukraine
Ph: +380 44 4909356, fax: +380 44 4909357
export@contact-endoscopy.com
www.contact-endoscopy.com

Name and address of the Authorized Representative:
EMBITRON s.r.o.
č.p. 290, 330 23 Vochov, Czech Republic
Ph: +420 371 511 600
embitron@embitron.cz
www.embitron.cz

This declaration of conformity is issued under the sole responsibility of the manufacturer

Subject of the declaration:
Medical Cart SPM-001.2

Classification according to the MDD 93/42/EEC/A5 Directive as amended:
Class I, Rule 1

The subjects of the declaration described above are in conformity with the relevant EU harmonized legislation:

Safety: **EN 60601-1:2006; A12:2014**

Notified Body: **CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.**
H-2040 Budaörs, Gyár u. 2., Hungary
Notified Body No 2409

Additional information:
The products as stated above comply with requirements of Annex II excluding (4) of MDD 93/42/EEC/A5 Directive as amended

Certificate	Reg. No.	Valid until
MSZ EN ISO 13485:2016	144994-20-04-15	14.04.2023

Valid until: **14.04.2023**

Place and date of issue:
Kyiv, 15.04.2020

ТОВАРИСТВО З ОБМЕЖЕНОЮ ВІДПОВІДАЛЬНІСТЮ
ФІРМА «КОНТАКТ»
Ідентифікаційний код 19422086
УКРАЇНА

General Manager
Mikhail Zagorovskyi