

#### 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	Туре	Intended use	Model	Risk class
Electrosurgical Generator unit	ECONT-0201.1	electrosurgical treatment	ECONT- 0201	11.00
	ECONT-0201.2			II.b
	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

Issue: 1

Issued: 18 May 2021 First issued: 18 May 2021

Start date of certified status: 18 May 2021

Expires:

25 May 2024

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

Valter PAPP, Dr. General Manager





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

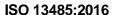
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CE Certiso Ltd. H-2092 Budakeszi, Erdő utca 101. Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu





### 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., Itd.

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

General Manager Mikhail Zagorovskyi