

**Kristóf Kovács**  
Director

Budapest, 14<sup>th</sup> November 2022  
Reference: NE/1041-28/2022

**CONTROL-X Medical Zrt.**  
Öv u. 29, 1141 Budapest, Hungary

## CONFIRMATION LETTER

NEOEMKI LLC. hereby confirms that CONTROL-X Medical Zrt. (address: Öv u. 29, 1141 Budapest, Hungary; company registration number: 01-10-142024) submitted a change notification for approval.

Affected certificate: 5-866-200-1906

Change request ID: NE/1041-26/2022

Date of notification of change request: 7<sup>th</sup> of November 2022

The change affected: quality management system, product documentation

Brief description of the change: transformation of the corporate legal form from limited liability company (kft.) to private limited company (zrt.)

Date of introduction of the change: 1<sup>st</sup> of November 2022

### Assessment of the significance of the change

Assessment of the submitted documents was made according to the qualification rules laid down in the MDCG 2020-3 guideline.

NEOEMKI LLC, the issuer of the certificate affected by the change, hereby confirm that **the change is qualified non-significant in the design or intended use of the device.**

Following the introduction of the change, the above mentioned certificate may remain valid, the products covered by the certificate may be lawfully placed on the market and put into service until conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 are met.

The effects of the change regarding the certified products and/or QMS, and the existence of all the conditions necessary to maintain the certificate shall be verified by the certification body as part of its surveillance activity.

This confirmation letter corrects or complements information on the affected certificate but does not represent the issuance of a "supplemented certificate" as this is prohibited under Article 120 (3) of Regulation (EU) 2017/745.

This confirmation letter is by no mean considered as a new, modified, amended, extended or supplemented certificate, as issuing of new certificates, including modified, amended or supplemented certificates is prohibited under Article 120 (3) of Regulation (EU) 2017/745.

This conformation letter has been issued upon request of the manufacturer and valid together with the corresponding certificate only.

  
Imre László  
Managing Director

