National Medical Device Conformity Assessment and Certification LLC.

Dr. Alkaysi Ghazi Khaled
CEO

Budapest, 9th January 2023
Reference: NE/1010-46/2023

Biotech GmbH
Hauptstraße 113, 56598 Rheinbrohl, Germany

CONFIRMATION LETTER

NEOEMKI LLC. hereby confirms that Biotech GmbH (seat address: Hauptstraße 113, 56598 Rheinbrohl, Germany) & Hungarian Branch (address: Petőfi Sándor u. 43-47, 2049 Diósd, Hungary, company registration number: 13-17-000066) submitted a change notification for approval.

Affected certificates: 5-903-200-2103, 5-904-204-2103, 5-905-204-2103, 5-927-204-2105
Change request ID: NE/1010-34/2022
Date of notification of change request: 6th of June 2022
The change affected: product documentation
Brief description of the change: new seat address
Date of introduction of the change: 19th of May 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 certificates affected by the change, hereby confirm that **the change is qualified non-significant in the design or intended use of the devices.**
Following the introduction of the change, the above mentioned certificates may remain valid, the products covered by the certificates 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 certificates shall be verified by the certification body as part of its surveillance activity.
This confirmation letter corrects or complements information on the affected certificates 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 new, modified, amended, extended or supplemented certificates, 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 certificates only.

Imre László
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

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