

# QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-561-135-2112

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.

as a Certification Body with ID No. NAH-4-0009/2021/K  
accredited by the National Accreditation Authority for management system certification  
certifies that the quality management system applied by

**BIOTECH GmbH**  
**Hagenauer Str. 17-19, 65203 Wiesbaden**  
**Germany**  
**and**  
**Magyarországi Fióktelepe**  
**Petőfi Sándor utca 43-47, 2049 Diósd**  
**Hungary**

meets the requirements of standard

**EN ISO 13485:2016**

in the field:

**Design, development, manufacture and distribution  
of non active surgical implant systems;  
Design, development, manufacture and distribution  
of surgical instrument systems**

Registry number of the related audit report: **NE/1010/2021**

This certificate is valid until **2024-09-08** supposed that the results of the regular yearly  
surveillance audits are satisfactory.

Budapest, 2021-12-30

  
László Imre  
Managing Director



EMKI 2796

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.  
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