

# QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-492-135-1809

The **Directorate of Device Testing and Clinical Engineering (EMKI)**  
as a Certification Body with ID No. NAH-4-0096/2016  
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: **43-066-2007**

This certificate is valid until **2021-09-08** supposed that the results of the regular yearly  
surveillance audits are satisfactory.

Budapest, 2018-09-09



Head of EMKI



EMKI 2092

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság  
*Directorate of Device Testing and Clinical Engineering*

H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33

E-mail: cert@emki.hu, Web: www.emki.hu

H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)